From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room 524
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 27 October 2000 (27.10.00)	
International application No. PCT/US00/06212	**Applicant's or agent's file reference** 16848.126.0
International filing date (day/month/year) 08 March 2000 (08.03.00)	**Priority date** (day/month/year) 08 March 1999 (08.03.99)
Applicant KUSLEIKA, Richard, S. et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

05 October 2000 (05.10.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The Internati nal Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Claudio Borton
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
16848.126.0		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 00/06212	08/03/2000	08/03/1999
Applicant		
MICROVENA CORPORATION et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

[ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

[ ] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readble form.

[ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [X] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

[X] the text is approved as submitted by the applicant.

[ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

[ ] the text is approved as submitted by the applicant.

[X] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 8

[ ] as suggested by the applicant.

[X] because the applicant failed to suggest a figure.

[ ] because this figure better characterizes the invention.

[ ] None of the figures.

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

The present invention provides a medical device retrieval system comprising a working element carried by a flexible, elongate shaft, the working element having a proximal profile and the shaft extending proximally from the working element and a retrieval cover slidably carried along the shaft of the medical device, the cover having a deployed configuration and being capable of being compressed into a compressed configuration for deployment, yet resiliently substantially return to the deployed configuration; the cover in its deployed configuration having a radially reduced proximal portion, a distally open distal end defining a distal opening having a maximum dimension at least as great as the maximum dimension of the proximal profile of the working element of the medical device, and an elongate internal recess defined between the proximal portion and the distal end.

INTERNATIONAL SEARCH REPORT

International Application No
US 00/06212

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/01 A61B17/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5 102 415 A (VORWERK DIERK ET AL) 7 April 1992 (1992-04-07) the whole document	1-3 7,8
Y A	WO 91 11209 A (BOSTON SCIENT CORP) 8 August 1991 (1991-08-08) page 8, line 32 -page 9, line 15; figure 1	7,8 1
X A	US 5 662 671 A (PASTRONE GIOVANNI ET AL) 2 September 1997 (1997-09-02) abstract; figure 1	1-4 7,8
A	WO 96 01591 A (MICROVENA CORP) 25 January 1996 (1996-01-25) cited in the application abstract; figure 15	1-8

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 July 2000	12/07/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Hansen, S

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
P[redacted]/US 00/06212

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5102415 A	07-04-1992	DE 8910603 U	07-12-1989
		CH 682978 A	31-12-1993
WO 9111209 A	08-08-1991	US 5041093 A	20-08-1991
		CA 2073858 A	01-08-1991
		DE 69125476 D	07-05-1997
		DE 69125476 T	27-11-1997
		EP 0513198 A	19-11-1992
		JP 5505118 T	05-08-1993
US 5662671 A	02-09-1997	AU 3888097 A	09-02-1998
		EP 0930842 A	28-07-1999
		US 5997557 A	07-12-1999
		WO 9802084 A	22-01-1998
		US 6010522 A	04-01-2000
		US 5895399 A	20-04-1999
		US 5993469 A	30-11-1999
WO 9601591 A	25-01-1996	CA 2194671 A	25-01-1996
		EP 0769926 A	02-05-1997
		EP 0902704 A	24-03-1999
		JP 10504738 T	12-05-1998
		WO 9726939 A	31-07-1997

INTERNATIONAL SEARCH REPORT

Inte[redacted]Application No
PCT/US 00/06212

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/01 A61B17/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 102 415 A (VORWERK DIERK ET AL) 7 April 1992 (1992-04-07)	1-3
Y	the whole document	7,8
Y	WO 91 11209 A (BOSTON SCIENT CORP) 8 August 1991 (1991-08-08)	7,8
A	page 8, line 32 -page 9, line 15; figure 1	1
X	US 5 662 671 A (PASTRONE GIOVANNI ET AL) 2 September 1997 (1997-09-02)	1-4
A	abstract; figure 1	7,8
A	WO 96 01591 A (MICROVENA CORP) 25 January 1996 (1996-01-25) cited in the application abstract; figure 15	1-8

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 July 2000	12/07/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Hansen, S

1

Form PCT/ISA/210 (second sheet) (July 1992)

PATENT COOPERATION TREATY

19 APR 2001

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

HOWE, Steven
LLOYD WISE, TREGEAR & CO.
Commonwealth House
1-19 New Oxford Street
London WC1A 1LW
GRANDE BRETAGNE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	17.04.2001
Applicant's or agent's file reference 16848.126.0	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US00/06212	08/03/2000	08/03/1999

Applicant
MICROVENA CORPORATION et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

   The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

   Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

   For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Nilles, F Tel.+49 89 2399-2931

Form PCT/IPEA/416 (July 1992)

44847

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
16848.126.0		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US00/06212	08/03/2000	08/03/1999
International Patent Classification (IPC) or national classification and IPC A61F2/01		
Applicant MICROVENA CORPORATION et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☐ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
05/10/2000	17.04.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Dhervé, G Telephone No. +49 89 2399 2415

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/06212

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-32 as originally filed

Claims, No.:

1-9 as originally filed

Drawings, sheets:

1/14-14/14 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1-9.

because:

☒ the said international application, or the said claims Nos. 9 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-8 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 9.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separat sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

III. Non-establishment of opinion with regard to novelty, inventiv step and industrial applicability

III.1. No meaningful opinion can be formed with regard to novelty, inventive step and industrial applicability of **claims 1-8** (Article 35(3)(a)PCT) for the following reasons.

Although claims 1, 7 and 8 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter, namely a medical device retrieval system and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and in respect of the terminology used for the features of that subject-matter. This presentation of a plurality of independent claims makes it difficult, if not impossible to determine the matter for which protection is sought, and places an undue burden on other seeking to establish the extent of the protection. The aforementioned claims therefore lack conciseness and do not meet the requirements of Article 6 PCT.
Consequently, the different combinations of features recited in the various independent claims do not allow to correctly identify "the claimed invention" on which an opinion should be based in the sense of Article 33(1) PCT.

In order to overcome this objection of lack of clarity and to avoid any objection of lack of unity (Rule 13.1 PCT), it would have been appropriate to file an amended set of claims defining the relevant subject-matter in terms of a single independent claim followed by dependent claims covering features which are merely optional (Rule 6.4 PCT).

In view of the further prosecution of the application the following remarks appear appropriate. A medical device retrieval system as defined in the first independent claim is shown in both prior art documents US-A-5 102 415 (see figures 2, 4 and the abstract) and US-A-5 662 671 (see the abstract and figure 1). It is further to be noted that these documents also show a retrieval sheath (additional feature defined in claims 2-4, 7 and 8 of the present application)

III.2. No international preliminary examination is carried out on **claim 9** because it relates to a "method of retrieving particulate or other foreign material within a channel of a patient's body" which involves a treatment of the living body by surgery and thus is covered by the provision of Article 35(3)(a) PCT and Rule 67(1)(iv) PCT.

VII. Certain defects in th international application

VII.1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents US-A-5 102 415 and US-A-5 662 671 is not mentioned in the description, nor are these documents identified therein.

VII.2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

VII.3. The mention "incorporated herein by reference" on page 2, lines 17, 18, should have been deleted (see the PCT Guidelines, II-4.17).

VII.4. The unit of measure employed on page 21, line 18, should have been additionally ex- pressed in terms of the units stipulated by Rule 10.1(a) PCT.

VII.5. Minor defects in the description:

- page 6, line 25, "figures 12" should have been corrected into "figures 1-2";
- page 19, line 24, "figure 11" should have been corrected into "figure 1B";
- page 29, line 10, reference sign 15 should have been corrected into 14.

VIII. Certain observations on the international application

The vague and imprecise statement in the description on page 32, last paragraph, especially the mention to "the spirit of the invention", implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity of the claims (Article 6 PCT) when used to interpret them (see also the PCT Guidelines, III-4.3a).

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
16848.126.0		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US00/06212	08/03/2000	08/03/1999
International Patent Classification (IPC) or national classification and IPC A61F2/01		
Applicant MICROVENA CORPORATION et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☐ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
05/10/2000	17.04.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Dhervé, G Telephone No. +49 89 2399 2415

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/06212

I. Basis of th report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-32 as originally filed

Claims, No.:

1-9 as originally filed

Drawings, sheets:

1/14-14/14 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application.

   ☒ claims Nos. 1-9.

because:

   ☒ the said international application, or the said claims Nos. 9 relate to the following subject matter which does not require an international preliminary examination (*specify*):
   see separate sheet

   ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-8 are so unclear that no meaningful opinion could be formed (*specify*):
   see separate sheet

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 9.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the standard.

   ☐ the computer readable form has not been furnished or does not comply with the standard.

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. C rtain observations on the internati nal application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

III. Non-establishment of opinion with r gard to nov lty, inv ntive step and industrial applicability

III.1. No meaningful opinion can be formed with regard to novelty, inventive step and industrial applicability of **claims 1-8** (Article 35(3)(a)PCT) for the following reasons.

Although claims 1, 7 and 8 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter, namely a medical device retrieval system and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and in respect of the terminology used for the features of that subject-matter. This presentation of a plurality of independent claims makes it difficult, if not impossible to determine the matter for which protection is sought, and places an undue burden on other seeking to establish the extent of the protection. The aforementioned claims therefore lack conciseness and do not meet the requirements of Article 6 PCT.
Consequently, the different combinations of features recited in the various independent claims do not allow to correctly identify "the claimed invention" on which an opinion should be based in the sense of Article 33(1) PCT.

In order to overcome this objection of lack of clarity and to avoid any objection of lack of unity (Rule 13.1 PCT), it would have been appropriate to file an amended set of claims defining the relevant subject-matter in terms of a single independent claim followed by dependent claims covering features which are merely optional (Rule 6.4 PCT).

In view of the further prosecution of the application the following remarks appear appropriate. A medical device retrieval system as defined in the first independent claim is shown in both prior art documents US-A-5 102 415 (see figures 2, 4 and the abstract) and US-A-5 662 671 (see the abstract and figure 1). It is further to be noted that these documents also show a retrieval sheath (additional feature defined in claims 2-4, 7 and 8 of the present application)

III.2. No international preliminary examination is carried out on **claim 9** because it relates to a "method of retrieving particulate or other foreign material within a channel of a patient's body" which involves a treatment of the living body by surgery and thus is covered by the provision of Article 35(3)(a) PCT and Rule 67(1)(iv) PCT.

VII. Certain d fects in th international application

VII.1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents US-A-5 102 415 and US-A-5 662 671 is not mentioned in the description, nor are these documents identified therein.

VII.2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

VII.3. The mention "incorporated herein by reference" on page 2, lines 17, 18, should have been deleted (see the PCT Guidelines, II-4.17).

VII.4. The unit of measure employed on page 21, line 18, should have been additionally ex- pressed in terms of the units stipulated by Rule 10.1(a) PCT.

VII.5. Minor defects in the description:

- page 6, line 25, "figures 12" should have been corrected into "figures 1-2";
- page 19, line 24, "figure 11" should have been corrected into "figure 1B";
- page 29, line 10, reference sign 15 should have been corrected into 14.

VIII. Certain observations on the international application

The vague and imprecise statement in the description on page 32, last paragraph, especially the mention to "the spirit of the invention", implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity of the claims (Article 6 PCT) when used to interpret them (see also the PCT Guidelines, III-4.3a).

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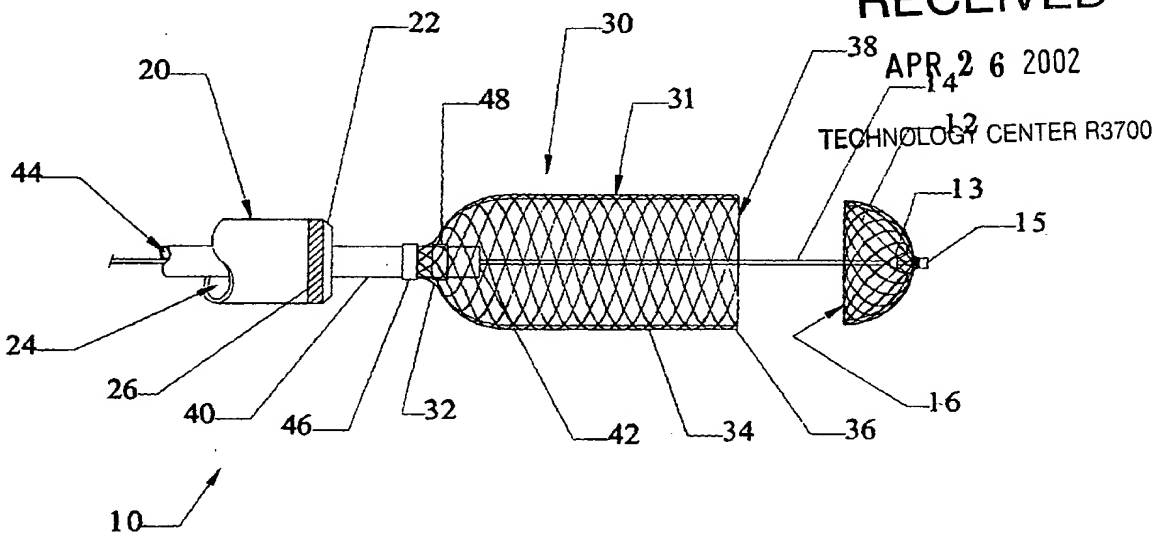
[Continued on next page]

(54) Title: MINIMALLY INVASIVE MEDICAL DEVICE DEPLOYMENT AND RETRIEVAL SYSTEM



(57) Abstract: The present invention provides a medical device retrieval system comprising a working element carried by a flexible, elongate shaft, the working element having a proximal profile and the shaft extending proximally from the working element and a retrieval cover slidably carried along the shaft of the medical device, the cover having a deployed configuration and being capable of being compressed into a compressed configuration for deployment, yet resiliently substantially return to the deployed configuration; the cover in its deployed configuration having a radially reduced proximal portion, a distally open distal end defining a distal opening having a maximum dimension at least as great as the maximum dimension of the proximal profile of the working element of the medical device, and an elongate internal recess defined between the proximal portion and the distal end.

WO 00/53120 A1

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MINIMALLY INVASIVE MEDICAL DEVICE DEPLOYMENT AND RETRIEVAL SYSTEM

FIELD OF THE INVENTION

The present invention generally relates to minimally invasive surgical procedures, e.g., angioplasty and atherectomy procedures, and has particular utility in connection with retrieving a medical device which has already been deployed. In one embodiment, the invention provides a vascular filter which can be retrieved with minimal risk of dumping the entrained contents back into the patient's bloodstream.

BACKGROUND OF THE INVENTION

In some medical procedures, a minimally invasive medical device is used to capture or dislodge material from within a patient's vascular system or other body vessel. For example, in certain procedures, balloon catheters are positioned such that the deflated balloon is placed distally of a vascular occlusion. Typically these vascular occlusions are relatively soft, uncalcified deposited along the walls of an artery. The balloon then may be inflated and drawn proximally. This will tend to dislodge any atheromatous material and withdraw it proximally with the balloon. In current procedures, an aspiration catheter will be moved distally into position adjacent the balloon and will be used to aspirate the dislodged material from the vessel.

A number of other minimally invasive surgical procedures are being used to treat vascular occlusions. These procedures include rotational atherectomy and balloon angioplasty. With the increasing use of vascular stents, it has been discovered that tissue or other material may build up inside a stent, reducing the patency of the vessel through the stent. In the course of improving the patency of the blood vessel utilizing these techniques, there is a risk that the material which was formally causing the obstruction within the vessel can simply float downstream with the flow of blood to the vessel. Accordingly, there is an

increasing recognition of the value of taking steps to capture the dislodged material.

A number of researchers have proposed various traps or filters for capturing the particulate matter or other embolic particles let loose in such procedures. Some filters are permanently implanted within the vessel. Emboli trapped within the filter are either aspirated out of the interior of the filter or are dissolved using drugs. Other filters are intended to be temporary in nature, typically being removed after the angioplasty, atherectomy or other procedure is complete. Generally, the goal is to retract the filter with the thrombi trapped therein. Unfortunately, many designs of such temporary filters may get relatively difficult or complex to retract the trap back in to the catheter through which it was delivered without simply dumping the trapped thrombi back in to the bloodstream.

One particularly advantageous vascular filter is shown in co-pending U.S. Patent Application No. 08/272,425, and International Patent Application No. PCT/US95/08613, which was published as International Publication No. WO 96/01591, the teachings of which are specifically incorporated herein by reference.

Figures 11-16 of WO 96/01591 are attached hereto as Figures 1-6 of the present application. Figure 1 is a vascular trap which is suitable for use in temporarily filtering embolic particles and the like from blood passing through a patient's vascular system. This device would most frequently be used to filter emboli from a patient's blood when another medical procedure is being performed, such as by using the trap in conjunction with a rotating cutting blade during an atherectomy, with a balloon catheter during angioplasty, or with a device used to clear the lumen of a stent during a stent cleaning procedure. It is to be understood, though, that the trap could also be used in other similar applications, such as in channels in patient's bodies other than their vascular systems.

The vascular trap 250 of Figures 1A and 1B comprises a generally umbrella-shaped basket 270 carried adjacent a distal end of a guidewire 260. The guidewire in this embodiment includes a tapered distal section 262 with a spirally wound coil 264 extending a distal length of the wire. Guidewires having such a distal end are conventional in the art. The basket 270 is positioned generally distally of the coil 264, and is desirably attached to the guidewire approximately with the proximal end of the tapered section as shown in these drawings.

The basket 270 of the device shown in WO 96/01591 (shown in its collapsed configuration in Figure 1A) includes a distal band 272 and a proximal band 274. The distal band may be made of a radiopaque material, such as gold, platinum or tungsten, and is affixed directly to the shaft of the guidewire 260. This attachment may be made by any suitable means, such as by welding, brazing or soldering. Alternatively, the distal band 272 may comprise a bead of a biocompatible cementitious material, such as a curable organic resin. WO 96/01591 teaches that a radiopaque metal or the like can be imbedded in the cementitious material to increase the visibility of the band for fluoroscopic observation. The proximal band 274 may be formed of a hypotube sized to permit the tube to slide along the guidewire during deployment. The inventors of that prior application suggest that the hypotube be made of a metallic material; a thin-walled tube of a NiTi alloy should suffice. If so desired, the proximal band may be formed of a more radiopaque metal, or a NiTi alloy band can have a radiopaque coating applied to its surface.

As taught in some detail in WO 96/01591, the basket 270 taught therein is formed of a metal fabric. The metal fabric of this embodiment is optimally initially formed as a tubular braid and the ends of the wires forming the braid can be attached together by means of the bands 272, 274 before the fabric is cut to length. These bands 272, 274 will help prevent the metal fabric from unraveling during the forming process. (The method of forming the basket 270 is described in great detail in WO 96/01591 and this process is still believed to provide a

suitable means for creating such a basket. The process is also discussed briefly below in connection with Figure 6.)

When the device is in its collapsed state for deployment in a patient's vessel (as illustrated in Figure 1A), the basket 270 of this device is said to be collapsed toward the axis of the guidewire 260. The distal 272 and proximal 274 bands are spaced away from one another along the length of the guidewire, with the fabric of the device extending therebetween. This publication teaches it is preferred that the basket is in its collapsed engages the outer surface of the guidewire to permit the device to be deployed through a relatively small lumen of a catheter or another medical device.

When the device is deployed in a patient's vascular system, the basket will take on an expanded configuration wherein it extends outwardly of the outer surface of the guidewire. As best seen in Figure 1B, the shape of the basket 270 when deployed may generally resemble a conventional umbrella or parachute, having a dome-like structure curving radially outwardly from the guidewire moving proximally from the distal band 272. It is to be understood that other suitable shapes could easily perform the desired filtering function, such as a conical shape wherein the slope of the device changes more linearly than the smooth, rounded version shown in Figure 1B. A relatively flat, disc shape may also suffice, but it is preferred that the device have a cavity or recess (discussed below) to better retain emboli or other material captured thereby. In this expanded configuration, the two bands 272, 274 are closer together, with the distal band 272 optimally being spaced only a short distance from the proximal band 274, as illustrated.

In moving from its collapsed state (Figure 1A) to its expanded state (Figure 1B), the metal fabric of this device turns in on itself, with a proximal portion 282 of the collapsed basket being received within the interior of a distal portion 284 of the collapsed basket. This produces a two-layered structure having a proximal lip 286 spaced radially outwardly of the guidewire, defining a proximally-facing cup-shaped cavity 288 of the basket. When blood (or any other fluid) flows through the basket in a distal direction, any particulate matter in

the blood, e.g. emboli released into the bloodstream during atherectomy or angioplasty procedures, will tend to be trapped in the cavity 288 of the basket.

WO 96/01591 teaches that the precise dimensions of the metal fabric can be varied as desired for various applications. If the device 250 is to be used as a vascular filter to trap emboli released into the blood, for example, this reference teaches that the pores (i.e. the openings between the crossing metal strands) of the fabric are desirably on the order of about 1.0 mm. These inventors deemed this to be the minimum size of any particles which are likely to cause any adverse side effects if they are allowed to float freely within a blood vessel. They teach that the pores should not be too small, though, because the blood (or other fluid) should be free to pass through the wall of the basket 270. If so desired, the basket may be coated with a suitable anti-thrombogenic coating to prevent the basket from occluding a blood vessel in which it is deployed.

When a fabric having 1.0 mm pores is used to form this basket 270, the forming process reorients the wires relative to one another and in some areas (e.g. adjacent the proximal lip 286) the pores tend to be larger than 1.0 mm. However, because the basket's walls are formed of essentially two thicknesses 282, 284 of the fabric, the effective pore size of the device may be significantly reduced even at these locations.

The device 250 of Figures 11 is also provided with tethers 290 for collapsing the basket 270 during retraction. The basket may include four independent tether wires, each of which extends proximally from the proximal lip 286 of the deployed basket. The authors suggested, though, that the four tether wires illustrated in the drawings be formed of two longer wires, with each wire extending peripherally about a portion of the proximal lip of the basket. These tether wires may be intertwined with the wires of the metal fabric to keep the tethers in place during use. When such tethers are retracted or drawn down toward the guidewire, the wires extending along the proximal lip of the basket will tend to act as drawstrings, drawing the proximal end of the basket radially inwardly toward the guidewire. This tends to close the basket and entrap any

material caught in the cavity 288 of the basket during use so that the basket can be retracted without the use of a cover.

The tether wires 290 may extend along much of the length of the guidewire so that they will extend outside the patient's body during use of the device 250. When it is desired to collapse the basket for retrieval, the operator can simply hold the guidewire 260 steady and retract the tethers with respect to the guidewire. This can tend to be relatively cumbersome, though, and may be too difficult to effectively accomplish without breaking the tethers if the device is deployed at a selective site reached by a tortuous path, such as in the brain.

To address this issue, the authors suggest, as shown in Figures 1A and 1B, that the tethers 290 be attached to the guidewire 260 at a position spaced proximally of the basket. The tethers may, for example, be attached to a metal strap 292 or the like and this strap 292 may be affixed to the shaft of the guidewire. When it is desired to close the proximal end of the basket for retraction, they suggest urging an external catheter (not shown) distally toward the basket 270. When the catheter encounters the radially extending tethers, the distal end of the catheter will tend to draw the tethers toward the guidewire as the catheter is advanced, which will, in turn, tend to draw the proximal end of the basket closed.

Figures 2A and 2B illustrate an alternative embodiment of the device shown in Figures 1A and 1B, also in accordance with the teachings of WO 96/01591. Figure 2A shows the device collapsed in a catheter C for deployment while Figure 2B shows the device in its deployed configuration. In Figures 2A and 2B, the basket 270 is much the same as that outlined above in connection with Figures 1A and 1B. In the embodiment of Figures 12, though, the distal band 272 is affixed to the guidewire 260' at the distal tip of the guidewire. The guidewire 260' is of the type referred to in the art as a "movable core" guidewire. In such guidewires, a core wire 265 is received within the lumen of a helically wound wire coil 266 and the core wire 265 extends distally beyond the distal end of the coil 266. A thin, elongate safety wire 268 may extend along the entire lumen of the coil 266 and the distal end of the safety wire may be attached to

the distal end of the coil to prevent loss of a segment of the coil if the coil should break.

In the embodiment of Figures 1 A and 1B, the proximal ends of the tethers 290 are attached to a metal strap 292 which is itself attached the shaft of the guidewire 260. In Figures 2A and 2B, the tethers are not attached to the core wire 265 itself. Instead, the tethers are attached to the coil 266 of the guidewire. The tethers may be attached to the coil by any suitable means, such as by means of laser spot welding, soldering or brazing. The tethers 290 may be attached to the coil 266 at virtually an spot along the length of the coil. As illustrated in these drawings, for example, the tethers may be attached to the coil adjacent the coil's distal end. However, if so desired the tethers may be attached to the coil at a location space more proximally from the basket 270.

An external catheter such as that referred to in the discussion of Figures 1A, but not shown in that figure, is illustrated in Figures 2A and 2B. Once the basket 270 is deployed in a patient's vessel to substantially reach the expanded configuration shown in Figure 2B and the basket has performed its intended filtration function, the external catheter C can be urged distally toward the basket 270. As this catheter is urged forward, the tethers will tend to be drawn into the distal end of the catheter, which is substantially narrower than the proximal lip 286 of the basket. This will tend to draw the tethers down toward the guidewire and help close the basket, as explained above.

Figures 3-5 illustrate yet another alternative embodiment of a vascular trap in accordance with WO 96/01591. This vascular trap 300 includes a basket 320 received over a guidewire 310. In most respects, the basket 320 is directly analogous to the basket 270 illustrated in Figures 1-2. The basket 320 includes a proximal band 322 and a distal band 324. As in the device of Figures 2A and 2B, the distal band may be attached to the guidewire adjacent its distal end. If so desired, though, a structure such as is shown in Figures 1A and 1B, wherein the guidewire extends distally beyond the basket, could instead be used.

As best seen in its collapsed state (shown in Figure 3), the basket includes a distal segment 325 and a proximal segment 326, with the distal end

of the distal segment being attached to the distal band 324 and the proximal end of the proximal segment being attached to the proximal band 322. When the basket 320 is in it expanded configuration (shown in Figure 4), the proximal segment 326 is received within the distal segment 325, defining a proximal lip 328 at the proximal edge of the device. The wall of the basket thus formed also includes a cavity 329 for trapping solids entrained in a fluid, such as emboli in a patient's blood stream.

The basket 320 of Figures 3-5 is also shaped a little bit differently than the basket 270 of the previous drawings. The primary difference between these two baskets is that the basket 320 is a little bit shorter along its axis that is the basket 270. This different basket shape is simply intended to illustrate that the basket of a vascular trap in accordance with the invention can have any of a wide variety of shapes and no particular significance should be attached to the slightly different shapes shown in the various drawings.

In the vascular traps 250 and 250' of Figures 1 and 2, respectively, tethers were used to draw down the proximal end of the basket 270 to close the basket for retraction. In the embodiment shown in Figures 3-5, though, the trap 300 includes a basket cover 340 positioned proximally of the basket 320. The basket cover may also be formed of a metallic tubular braid and is also adapted to be collapsed to lay generally along the outer surface of the guidewire 310. The cover 340 is not directly affixed to the guidewire at any point, though, but is instead intended to be slidable along the guidewire. As best seen in Figures 3 and 4 wherein the cover is in its collapsed state, the cover 340 includes a distal hypotube 342 and a proximal control hypotube 344, with the distal hypotube being attached to the distal end of the cover 340 and the proximal control hypotube 344 being attached to the proximal end of the cover.

The cover 340 is shown in its deployed, expanded configuration in Figure 5. As shown in that figure, the cover has a similar structure to that of the basket 320, but is oriented to be open distally rather that proximally, as is the basket. As best seen in Figures 3 and 4 wherein the cover is in its collapsed state, the cover has a distal segment 352 and a proximal segment 354. When the cover is

deployed by urging it distally out of the distal end of the deployment catheter C, the cover 340 will tend to resiliently return to its expanded configuration and the distal hypotube 342 will slide axially proximally along the guidewire toward the proximal control hypotube 344. This will invert the collapsed cover so that the distal section 352 is generally received within the proximal section 354, defining a distal lip 358 of the cover.

WO 96/01591 teaches that the proximal control hypotube 344 of this cover may extend along a substantial portion of the length of the catheter 310 so that it extends out of the patient's body when the device 300 is in place. By grasping the control hypotube and moving it relative to the guidewire 310, an operator can control the position of the cover 340 with respect to the basket 320, which is affixed to the guidewires. As explained in more detail below in connection with the use of the device 300, once the basket has been deployed and has been used to filter objects entrained in the fluid (e.g. emboli in blood), the cover 340 may be deployed and the trap may be drawn proximally toward the cover by moving the guidewire proximally with respect to the control hypotube 344.

The inner diameter of the distal lip 358 of the cover is desirably slightly larger than the outer diameter of the proximal lip 328 of the basket. Hence, when the basket is drawn proximally toward the cover it will be substantially enclosed therein. The cover will therefore tend to trap any emboli (not shown) or other particulate matter retained within the cavity 330 of the basket. A retrieval sheath S may then be urged distally to engage the outer surface of the cover 340. This will tend to cause the cover to collapse about the basket, tightly engaging the outer surface of the basket. This somewhat collapsed structure can then be withdrawn from the patient's channel and removed from the patient's body. By enclosing the basket within the cover, the likelihood of any filtered debris within the basket being lost as the basket is retrieved will be substantially eliminated.

Figure 6 illustrates the molding element 370 suggested in WO 96/01591 for use in making a basket 270. Although the basket 320 and cover 340 of the

trap 300 are shaped somewhat differently, an analogous molding element can be used for these portions of the trap 300 as well by simply modifying some of the dimensions of the molding element 370, but retaining the basic shape and structure of the molding element. It also should be understood that the molding element 370 is merely one possible molding element for forming a shape such as that of the basket 270 and WO 96/01591 teaches a variety of different molding elements and notes that other designs will be apparent to those skilled in the art.

The molding element 370 of Figure 6 has an outer molding section 372 defining a curved inner surface 374 and an inner molding section 376 having an outer surface 378 substantially the same shape as the curved inner surface 374 of the outer molding section. The inner molding section 376 should be sized to be received within the outer molding section, with a piece of the metal fabric (not shown) being disposed between the inner and outer molding sections. In a preferred embodiment, the inner surface 374 of the outer molding element and the outer surface 378 of the inner molding section each include a recess (375 and 379, respectively) for receiving an end of the braid. The molding surface of this molding element 370, to which the fabric will generally conform, can be considered to include both the inner surface 374 of the outer molding section and the outer surface 378 of the inner molding section.

WO 96/01591 teaches that the two molding sections 372, 376 are spaced apart from one another and a length of a tubular braid of metal fabric (not shown in Figure 6) is disposed between these molding sections. Optimally, one end of the fabric is placed in the recess 375 of the outer molding section and the other end of the fabric is placed in the recess 379 in the inner molding section. As noted above, the ends of the tubular fabric can be clamped prior to this molding process to limit the likelihood that the fabric will unravel. The inner and outer molding sections can then be urged generally toward one another. As the ends of the wire approach one another, the tubular braid will tend to invert upon itself and a surface of the tubular braid will generally conform to either the inner surface 374 of the outer molding section or the outer surface 378 of the inner

molding section, arriving at a shape analogous to that of the basket 270 of the traps 250, 250'. The two molding sections can them be locked in place with respect to one another and the metal fabric may be heat treated to set the wires in this deformed configuration.

This published international application also teaches how one may use the traps 250, 250' and 300 taught therein. It suggests that these traps be deployed for use in conjunction with another medical device and that they will most frequently be retracted from the patient's body after use. WO 96/01591 uses a balloon angioplasty procedure and an atherectomy procedures as contexts for illustrating a method of using such traps. In balloon angioplasty, balloon catheters having inflatable balloons at their ends are positioned within a blood vessel so that the balloon is positioned within a stenosis. These balloons are positioned by tracking the balloon catheter along a guidewire or the like; the balloons typically have a central bore therethrough. Once the balloon is properly positioned, it is inflated and urges radially outwardly against the stenosis. This will tend to squeeze the stenosis against the walls of the vessel, improving patency of the vessel.

When the stenosis is treated in this fashion, though, there is a risk that some debris will break free and enter the blood flowing through the vessel. If left unchecked, this embolus can drift downstream and embolize a distal portion of the vessel. Depending on where the embolus comes to rest, the embolization can result in significant tissue or organ damage. In order to prevent, or at least substantially limit, such embolization, WO 96/01591 suggests the use of a vascular trap 250, 250' or 300 of with the balloon catheter. The device should be sized to permit it to be passed through the lumen of the particular balloon catheter to be used in the angioplasty.

In one method taught in WO 96/01591, the trap is deployed first. The basket (270 or 320) of the trap is guided to a position located downstream of the desired treatment site through an introduction catheter (e.g. the catheter C in Figures 12-15). The basket is then urged distally beyond the end of the catheter, which permits the basket to resiliently substantially return to its

expanded configuration from its collapsed configuration within the catheter. Once the trap is in place, the balloon catheter can be exchanged for the introduction catheter, and the balloon catheter can track the guidewire (260 or 310) of the vascular trap. The balloon can then be positioned within the stenosis and expanded, as outlined above. Once the angioplasty has been completed, the balloon can be deflated again and withdrawn proximally out of the patient.

WO 96/01591 also explains that the balloon catheter can be used to perform the same function as performed by the introduction catheter in the preceding embodiment. In this embodiment, the balloon catheter is positioned in the patient's vessel so that the distal end of the balloon catheter is located downstream of the stenosis. The vascular trap (250, 250' or 300) of the invention is then passed through the lumen of the balloon catheter and the basket is urged out of the distal end of the catheter. The basket will resiliently substantially return to its preferred expanded configuration, whereupon the balloon catheter can be retracted along the shaft of the device's guidewire until the balloon is properly positioned within the stenosis.

If so desired, the balloon catheter can instead be provided with a length of standard catheter extending distally beyond the distal end of the balloon. The balloon can then be positioned within the stenosis and the basket can be urged out of the distal end of the distal extension of the catheter. In such an embodiment, the length of the distal extension of the catheter should be sufficient to properly position the basket with respect to the balloon when the basket exits the distal end of the catheter. This will eliminate the need to perform the separate step of retracting the balloon into position within the stenosis after the basket is deployed. The balloon can then be expanded, deflated and withdrawn as described above.

WO 96/01591 teaches that much the same procedure can be used to deploy a vascular trap for use in an atherectomy procedure. In such procedures, a cutting head is positioned at the distal end of an elongate, hollow shaft and the cutting head has a bore extending therethrough. The trap can be deployed in either of the methods outlined above, but it is anticipated that in

most instances the first procedure will be used, i.e. the basket will be deployed with an introduction catheter, which will be removed so that the cutting device can be guided over the guidewire of the vascular trap. This publication also stresses that the device 250, 250' and 300 could be used in other medical procedures in other bodily channels besides a patient's vascular system.

Since the trap is positioned downstream of the stenosis, any debris released during one of these procedures will tend to drift distally toward the basket and be caught therein. In order to prevent any emboli from simply floating past the trap, it is preferred that the proximal lip (288 or 328) of the basket be at least as large as the lumen of the vessel. WO 96/01591 suggests that the natural dimension of the proximal lip (i.e. where the basket has fully returned to its expanded configuration) be made somewhat greater than the vessel's inner diameter so the basket will firmly engage the wall of the vessel.

The method of retracting the basket will depend on which embodiment of the vascular trap is used, namely whether or not the device includes a cover 340. The device 250 or 250' of Figures 1 or 2, respectively, do not include such a cover. However, they do include tethers 290 which extend proximally from the proximal lip 288 of the basket to an attachment to the guidewire. In either of these embodiments, a retrieval catheter can be introduced over the guidewire and urged distally toward the basket. As explained above in connection with Figures 1 and 2, this will tend to draw the tethers down toward the guidewire, effectively closing the proximal end of the basket 270. Once the basket is sufficiently closed, such as when the proximal lip of the basket engages the distal tip of the retrieval catheter, the catheter and the vascular trap can be retracted together from the patient's body. By substantially closing the proximal end of the basket in such a fashion, any emboli which are captured in the basket when it is deployed can be retained within the basket until it is removed from the patient's body.

If so desired, a balloon catheter or like device can instead be used, with the balloon catheter being used to draw down the tethers 290 and collapse the basket. The vascular trap can then be withdrawn with the balloon catheter

rather than having to separately introduce a removal catheter to remove the trap.

In withdrawing the embodiment illustrated in Figures 3-5, the cover 340 is positioned over the proximal lip of the basket before the vascular trap 300 is retracted. Once the medical procedure is completed and any debris has been captured in the basket, the cover 340 is allowed to resiliently substantially return to its expanded configuration. Once it is deployed proximally of the basket, the basket 320 can be drawn proximally toward the cover 340 until it engages or is received within the cover, as noted above in connection with Figure 5.

In actuality, the cover 340 of Figures 3-5 may be unable to return to its full expanded configuration due to the confines of the vessel in which it is deployed. As explained previously, the cover 340 is desirably larger than the basket 320 so that the basket can be received within the cover. However, the basket is optimally sized to engage the walls of the vessel to prevent the unwanted passage of emboli or other debris around the edges of the basket. Accordingly, the distal lip 358 of the cover will engage the wall of the channel before it expands to its full size. The walls of most bodily channels, such as blood vessels, tend to be somewhat elastic, though. The cover 340 will therefore tend to urge harder against the wall of the vessel than the smaller basket and may stretch the vessel a little bit more than will the basket. In this fashion, the cover may still be able to expand to a dimension large enough to permit the basket to be received in the cavity 356 of the cover. If not, the distal lip 358 of the cover can simply be brought into close engagement with the proximal lip 328 of the basket to generally seal the basket.

Once the cover 340 is brought into engagement with the basket 320, whether by receiving the basket within the cover or, less preferably, by engaging the lips 358, 328 of the cover and the basket, the device can be withdrawn proximally from the patient's vascular system. The cover will tend to prevent any emboli caught in the basket during deployment from being inadvertently lost during withdrawal.

The vascular traps 250, 250' and 300 shown in Figures 1-6 represent a significant advancement over previously available devices. The embodiment of Figures 3-5 shows particular promise in that the cover permits the user to withdraw the basket with the emboli entrained therein without having to take any additional precautions to minimize the chances that these emboli will be accidentally dumped back into the bloodstream.

SUMMARY OF THE INVENTION

The present invention provides a medical device retrieval system and a method of retrieving a medical device. In accordance with one embodiment of the invention, a medical device retrieval system includes a medical device and a retrieval cover. The medical device comprises a working element carried by a flexible, elongate shaft. The working element has a proximal profile and the shaft extends proximally from the working element. The retrieval cover is slidably carried along the shaft of the medical device. The cover has a deployed configuration and is capable of being compressed in a compressed configuration for deployment, yet resiliently substantially returned to the deployed configuration. The cover in its deployed configuration has a radially reduced proximal portion. A distally open distal end defining a distal opening having a maximum dimension at least as great as the maximum dimension on the proximal profile of the working element of the medical device, and an elongate internal recess defined between the proximal portion on the distal end. The cover in its compressed configuration is radially compressed inwardly toward the shaft and is distally open, with the distal end defining the distal-most portion of the cover. Optimally, the retrieval cover is designed to maintain this general orientation wherein the distal end of the device is always the distal-most portion of the cover, regardless of the configuration of the device.

This medical device retrieval system may further include a retrieval sheath which is slidable along the shaft of the medical device. Such a sheath, if included, is desirably positioned distally on the cover when the cover is in its deployed configuration. This retrieval sheath may have an inner diameter

smaller than the outer diameter of the cover in its deployed configuration. This sheath is adapted to slide distally along the cover to compress the cover about the medical device.

In accordance with a further embodiment, the present invention provides a medical device retrieval system which comprises a medical device, a retrieval sheath, a deployment stylet and a retrieval cover. The medical device comprises a working element carried by a flexible, elongate shaft having an outer diameter. The working element has a proximal profile and the shaft extends proximally from the working element. The retrieval sheath is slidable along the shaft of the medical device and optimally has a beveled distal end with a distal lumen. The deployment stylet is slidable along the shaft of the medical device and has a distal tip. This distal tip tapers distally from a first diameter approximating the diameter of the distal lumen of the sheath to a second diameter more closely approximating the outer diameter of the medical device shaft. This provides a transition between the shaft of the medical device and the distal end of the retrieval sheath when the deployment stylet is positioned such that a distal tip extends distally beyond the distal end of the retrieval sheath. The retrieval cover is slidable along the shaft of the medical device and is exchangeable for the stylet along that shaft. The cover has a deployed configuration and is capable of being compressed into a compressed configuration for sliding within the lumen of the retrieval sheath yet resiliently substantially return to the deployed configuration. In its deployed configuration, the cover has a radially reduced proximal portion, a distally open distal end, and an elongate internal recess defined between the proximal portion and the distal end. The distal end defines a distal opening having a maximum dimension at least as great as the maximum dimension of the proximal profile of the working element of the medical device. In its compressed configuration, the cover is radially compressed inwardly toward the shaft and is distally open, with the distal end defining the distal-most portion of the cover.

Another embodiment of the invention provides a retractable medical device system including a medical device, a retrieval cover and a retrieval

sheath. The medical device comprises a working element carried by a flexible, elongate shaft. The retrieval cover is slidable along the shaft of the medical device. The cover has a radially reduced proximal portion, a distally open distal end an elongate tubular wall extending therebetween and defining a recess. The working element of the medical device is completely retained within the recess of the cover such that the tubular wall extends distally beyond the medical device. The retrieval sheath has a lumen and is slidable with respect to both the medical device and the cover. At least a proximal length of the working element of the medical device and the cover are retained within the lumen of the retrieval sheath, with the retrieval sheath regularly compressing the proximal length of the cover such that an intermediate portion of the wall tightly engages the surface of the medical device. This will tend to effectively trap any emboli or other materials retained by the medical device.

As noted above, the present invention contemplates a method. One such method involves receiving particulate or other form material within a channel of a patient's body. As a first step in performing this method, one provides a medical device having a working element and a flexible, elongate shaft adapted to follow a path within the channel; a distally open cover slidable with respect to the shaft; and a retrieval sheath movable with respect to the cover on the shaft. The medical device is positioned within the vessel to engage a wall of the channel and trap the material within the channel. Either during such positioning or after the medical device has been positioned and while it is trapping material within the channel, the cover and the retrieval sheath may be positioned so they are spaced proximally of the working element along the shaft of the medical device. The cover is radially compressed within the lumen of the retrieval sheath such that it has a distally open distal end and a wall defining a recess, the wall engaging an inner surface of the retrieval sheath. The cover is moved distally with respect to the retrieval sheath, thereby permitting the cover to radially expand into a deployed configuration wherein the distal end remains distally open and the enclosure is radially expanded. The cover expands radially outwardly into the deployed configuration without having to invert on itself. The

cover is then moved distally into engagement with a surface of the medical device to form therebetween an enclosure. The retrieval sheath may then be moved distally with respect to the cover to urge to cover to collapse about the medical device and tightly engage the surface of the medical device.

BRIEF DESCRIPTION OF THE DRAWINGS

Figures 1A is a schematic side view in accordance with WO 96/01591, showing a vascular trap in a collapsed state for deployment in a patient's vascular system;

Figure 1B is a schematic side view of the medical device of Figure 1A in an expanded state for deployment in a patient's vascular system;

Figure 2A is a schematic side view in accordance with WO 96/01591, showing an alternative vascular trap in a collapsed state within a catheter for deployment;

Figure 2B is a schematic side view of the device of Figure 2A, showing the device deployed distally of the catheter;

Figure 3 is a schematic perspective view in accordance with WO 96/01591 showing a vascular trap and a cover, both of which are collapsed within a catheter for deployment in a channel in a patient's body;

Figure 4 is a schematic side view of the device of Figure 3 in a partially deployed state, wherein the vascular trap has been deployed, but the cover is still collapsed within the catheter;

Figure 5 is a schematic side view of the device of Figure 3 in a fully deployed state;

Figure 6 illustrates one embodiment of a molding element which may be used in making a portion of the vascular traps shown in Figures 1-5;

Figure 7 is a schematic illustration of a retrieval sheath catching on a vascular obstruction proximally of the desired distal deployment site;

Figure 8 is a schematic side view of a device in accordance with the present invention with both the trap and the cover fully deployed;

Figure 9 is a schematic cross sectional view showing the device of Figure 8 wherein the trap has been deployed but the cover has retained within the retrieval sheath;

Figure 10 is a schematic illustration showing the invention deployed within a patient's vessel and having emboli retained therein;

Figure 11 is view similar to Figure 10, but showing the trap being retracted into the confines of the cover;

Figure 12 is a schematic, partially cut away view of the device of Figures 10 and 11 showing the cover being retracted within the retrieval sheath;

Figure 13 is a schematic partial cross sectional view of a distal portion of a medical device retrieval system of the invention utilizing a deployment stylet; and

Figure 14 is a schematic side view of a distal length of an alternative retrieval sheath for use with the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figures 8-12 schematically illustrate the operation of one embodiment of the present invention. Figure 8 illustrates certain operative portions of the medical device retrieval system 10 of the invention in a fully deployed state. As noted above, the retrieval system of the invention is intended to be used in connection with a medical device having a working element carried by flexible, elongate shaft. In these drawings, the medical device is typified as a vascular trap similar to the vascular trap 250 of Figure 11, but omitting the tethers 290. The working element of this medical device is a basket 12, which may be substantially as outlined above in connection with the description of the basket 270. The shaft in this design may simply comprise a guidewire 14. While the construction and operation of the basket 12 may be substantially the same as

that outline for the baskets shown in Figures 1-5, it is generally preferred that the proximal band 13 of this basket be attached to the guidewire while the distal band 15 be permitted to slide along the guidewire. Hence, when the basket 12 is released from a delivery catheter and the basket is allowed to achieve a radially expanded configuration, the distal end of the collapsed device (272 in Figure 1A) will slide approximately toward the proximal end (274) of the collapsed device.

It should be recognized that the medical device can be varied as desired. For example, the medical device used in connection with the present retrieval system could instead by a balloon catheter, wherein the working element would be the balloon portion of the catheter and the shaft would comprise the body of the catheter extending proximally of the balloon.

The other elements of the retrieval system 10 generally comprise a retrieval sheath 20 and a cover 30. It is to be understood that these drawings are intended merely for illustrative purposes and are not drawn to scale. In actual operation, the retrieval sheath 20 and the shaft 40 of the cover would likely be much smaller. These elements are simply drawn larger to make the various components easier to see in the attached illustrations.

The cover 30 includes a radially expandable body 31 carried by a shaft 40. The body has a proximal portion 32 which is radially compressed into close proximity with the shaft 40 and is desirably attached directly thereto. A tubular wall 34 extends distally from the proximal portion and terminates in a distally open end 36. The body 31 defines a recess 38 within which the working element of the medical device may be retracted, as explained more fully below. The majority of the length of this recess is defined by the generally tubular wall 34.

This radially expandable body 31 can be formed of any suitable material. As explained more fully below, it is preferred that this body be capable of being collapsed within the retrieval sheath 20 for deployment, radially expand into a deployed configuration, yet be readily collapsed by the retrieval sheath to tightly

engage the working element of the medical device. Any material which achieves this function may be used.

In one embodiment (not shown), the body 31 is formed of a flexible plastic material, which may be reinforced with one or more flexible metal hoops or the like to bias the tubular plastic member into a funnel-like configuration.

The illustrated embodiment is shown as comprising a series of flexible metal wires. As explained in some detail in International Publication No. WO 96/01591, such a radially expandable device may be made rather conveniently utilizing a metal fabric having strands formed of a material which is both resilient and which can be heat treated to substantially set a desired shape. Materials such as elgiloy, hastelloy, incoloy, certain grades of stainless steel and shape memory alloys. Of these materials, shape memory alloy such as nitinol are particularly preferred.

In one useful embodiment, the radially expandable body 31 is formed using the techniques outlined in WO 96/01591, starting with a metal fabric comprising both nitinol and platinum. For example, the fabric may be a generally tubular fabric formed of 48 wires having a diameter on the order of about 0.0015 inches and a pic rate of about 80-100 pics per inch. Of the 48 wires used to form this metal fabric, a relatively small percentage of the wires (e.g. 4-6 wires) may be formed of platinum or some other relatively radiopaque material to enhance visibility of the device on a fluoroscope without unduly affecting the resiliency of the fabric. If so desired, the wires can be coated with a therapeutic agent or with an antithrombogenic material. For example, the wires may be coated with heparin or with a known platelet-deactivating drug, e.g., a 2B-3A antagonist.

This radially expandable body 31 is carried by a axially slidable shaft 40. This shaft may take the form of a metallic hypotube, such as that discussed in connection with the embodiment of Figures 3-5. More preferably, though, the shaft 40 comprises a flexible plastic material of the type that is commonly used in forming medical catheters. If friction of this shaft 40 with the retrieval sheath

20 and/or the shaft 14 of the medical device is anticipated to present a problem, this shaft 40 of the cover may be formed of polytetrafluoroethylene or another suitable low-friction material.

The radially expandable body 31 may be attached to the shaft 40 in any suitable manner. Presumably, the ends of the wires defining the body 31 could be simply cast into the plastic defining the flexible shaft 40. However, the embodiment shown in the drawings is somewhat easier to make, utilizing a pair of marker bands 46 and 48 to attach the body to the shaft by clamping the proximal end about the exterior of the sheath. Forming these clamps of a radiopaque material will make it easier to track the position of the cover 30 as it is deployed. In the illustrated embodiment, the cover comprises an exterior layer and an interior layer of the metal fabric, much like the basket 270 described above in connection with Figures 1-5. In this configuration, the proximal marker band 46 may be used to clamp the exterior layer of the metal fabric to the exterior of the shaft 40 while the distal marker band 48 is used to clamp the interior layer of the fabric to the shaft.

In the illustrated embodiment, the shaft 40 includes a lumen 44 through which the shaft 14 of the medical device is received, thereby permitting the cover 30 to track that shaft for deployment. The shaft 40 shown in Figures 8 and 9 extends distally beyond the distal marker band 48 such that the distal tip 42 of the shaft is received within the recess 38 of the cover. Not only will this make manufacturing easier, but it will reduce the likelihood that any guidewire or other device passing through the lumen 44 of the shaft 40 will get caught up in the metal fabric defining the radially expandable body 31.

The retrieval sheath 20 may simply take the form of a standard medical catheter, with a tip as described below. This sheath has a generally tubular wall defining a lumen 24 within which the shaft 14 of the medical device and the shaft 40 of the cover may be slidably received. The differences in the diameters of these three elements 20, 40 and 14 are exaggerated in Figures 8 and 9 to

illustrate operation of the device. In reality, these diameters would likely be substantially closer than those shown.

The distal tip 22 of the retrieval sheath 20 may be beveled to produce a smoother tip. (The advantage of this tip construction will be highlighted below in connection with the discussion of Figures 7, 13 and 14.) If so desired, a marker band 26 may be incorporated into the wall of the retrieval sheath 20 adjacent the distal tip 22. This will help an operator visualize the relative position of the retrieval sheath 20, the cover 30 and the basket 12 during operation.

Figure 9 is a schematic cross sectional view of the device illustrated in Figure 8 prior to deployment of the cover. In operation, the medical device will typically be put in place first. As outlined above in connection with Figures 1 and 2, the basket 12 may be positioned distally of a particular treatment site and the treatment device (e.g. a balloon catheter or an atherectomy device) can be guided over the shaft 14 of the trap to perform the intended procedure. In the use of the retrieval system of the invention with such a trap, one would typically deploy the retrieval sheath 20 and the cover 30 after the basket 12 has been in place for some time rather than deploying all three elements at substantially the same time. It should be understood, though, that simultaneous deployment may be appropriate in other circumstances, such as when a cover 30 and retrieval sheath 20 are used in connection with a Foley catheter or the like.

Whereas Figure 8 illustrates the cover in its deployed configuration, Figure 9 illustrates the cover in a compressed configuration which is suitable for deployment. Even in its compressed configuration, it can be seen that the body 31 of the catheter generally includes a radially reduced proximal portion 32, an elongate tubular wall 34 and a distally open distal end 36 which defines the distal-most portion of the cover. This is indirect contrast to the structure shown in Figures 3 and 4, which show the cover 340 of that device in its collapsed state. In this collapsed state, the cover 340 has a distal segment 352 and a proximal segment 354, both of which are generally tubular in shape and lie proximate the exterior surface of the guide wire 310. Once this cover is

deployed as shown in Figure 5, though, the cover must invert on itself to position the distal section 352 generally within the proximal section 354 to define a distal lip 358 of the cover. This distal lip 358 is merely an intermediate point along the longer, axially expanded configuration of the device when it is collapsed, as shown in Figures 3 and 4.

There are a number of advantages of the structure of the present cover 30 over the mechanically more complex design of Figures 3-5. In the cover 340 of Figures 3-5, the cover must invert on itself before it can be used to enclose the basket 320. The resilient nature of the metal fabric used to form the cover 340 will tend to resiliently draw the distal hypotube 342 proximally toward the proximal control hypotube 344 once the constraint of the deployment catheter C has been removed.

The walls of the vessel can hinder complete inversion of the cover 340, though. In particular, if the inner diameter of the vessel within which the cover is to be deployed is significantly smaller than the outer diameter of the fully deployed cover, the cover may take on a sausage-like configuration, with the distal and proximal segments 352, 354 of the cover expanding into engagement with the wall of the vessel, but being unable to expand sufficiently to allow the distal hypotube to invert the distal segment 352 so that it may be received within the proximal section 354. In such a circumstance, the cover will not define a suitable recess for receiving the basket 320 therein.

The design shown in Figures 8-12 does not require that the radially expandable body 31 invert on itself to reach its fully deployed configuration. Instead, the recess 38 will always remain in place. Deployment of the body 31 distally beyond the distal tip 22 of the retrieval sheath will simply allow this recess to expand to a size wherein it may readily receive the working element of the medical device with which the cover is used.

While Figures 8 and 9 schematically illustrate the structure of the device and its various elements, Figures 10-12 are intended to schematically illustrate the manner in which the cover 30 may be used to retrieve a basket 12 which is

full of emboli or other particular material. In Figure 10, the deployment catheter C (discussed above in connection with Figures 1-5) is shown extending into the lumen of the vessel and terminating proximally of the position of the basket 12. The cavity of the basket 12 is filled with emboli E. If one were to simply pull the guidewire 12 proximally, this will tend to evert the generally umbrella-shaped basket 12, raising the possibility that the emboli E could be dumped into the bloodstream of the vessel.

In Figure 10, the retrieval sheath 20 is positioned proximally of the basket 12, leaving a space between the distal tip 22 of the sheath 20 and the basket 12. In this Figure, the cover 30 is still within the lumen 24 of the retrieval sheath 20, much as in the configuration shown in cross section in Figure 9.

Once the retrieval sheath, with the cover retained therein, is properly positioned, the shaft 40 of the cover 30 may be advanced distally with respect to the sheath 20. This may be accomplished either by holding the sheath 20 stationary and advancing the shaft 40 of the cover distally or by holding the shaft 40 of the cover relatively stationary and withdrawing the retrieval sheath 20 proximally to expose the readily expandable body 31 beyond the distal tip 22 of the sheath 20.

When the body 31 of the cover exits the distal end of the retrieval sheath 20, it will tend to resiliently substantially return to the configuration schematically illustrated in Figure 8. Unlike the cover 340 of Figures 3-5, the body 31 of the present invention will begin to radially expand into its final shape as soon as the distal end 36 clears the distal tip 22 of the sheath 20. Accordingly, there is no need to deploy the cover 30 so that even the proximal marker band 46 is positioned distally of the distal tip 22 of the retrieval sheath as shown in Figure 8. Instead, the proximal portion 32 of the body 31 may remain within the lumen of the retrieval sheath 20, as suggested in Figure 11, without compromising operation of the cover 30.

Figure 11 illustrates the device wherein the cover has been sufficiently deployed to define a recess large enough to receive the body of the basket 12

therein. To achieve the configuration shown in Figure 11, the shaft 14 of the vascular trap is withdrawn proximally, drawing the basket 12 within the enclosure 38.

As noted above in connection with Figure 8, the presently preferred embodiment of such vascular trap employs a proximal band 13 which attaches a proximal end of the metal fabric defining the basket directly to the shaft of the guidewire 14 while the distal connector 15 is allowed to slide along the length of the shaft 14. Accordingly, when the operator pulls proximally on the guidewire 14, this will tend to elongate the trap and cause it to evert. In the absence of aspiration or a cover 30, this could present some difficulties.

Prior to withdrawing the shaft 14 proximally, the distal end 36 of the cover is desirally brought immediately adjacent the basket 12. In a preferred embodiment, the distal end 36 of the body 31 of the cover defines a distal opening having a maximum dimension which is at least as great as the maximum dimension of the proximal profile of the basket 12, i.e., the maximum dimension of the proximal projection of the deployed basket. If the vessel is large enough, this would permit the cover to simply slide around the basket 12 without significantly stressing the basket and causing it to collapse in any way. More likely than not, though, there will be insufficient clearance between the basket 12 and the wall of the vessel to permit the cover to readily slide between the vessel and the basket. Accordingly, the distal end of the cover will typically be brought into engagement with a surface of the basket 12. This will form between the cover and the basket and enclosure that includes both the cavity of the basket and the recess 38 of the cover. This movement of the cover distally into engagement with the medical device may be achieved either by actually physically moving the cover distally in an absolute sense, or simply withdrawing the basket 12 toward the cover which will effectively move the cover distally with respect to the medical device.

Figure 11 illustrates the relative positions of the elements of the invention if the operator continues to withdraw the guidewire 14 proximally after the cover

initially engages the surface of the basket 12. The basket has started to evert into a more oblong shape rather than the umbrella-shape shown in Figure 10. Nonetheless, the emboli still are retained within the enclosure defined by the cover and the basket.

In one preferred embodiment, the body 31 of the cover is at least as long as the working element of the medical device which is to be retrieved therewith. This permits the working element to be entirely enclosed by the cover during the retrieval process, enhancing the likelihood of a successful retrieval without inadvertent dumping of the matter captured by the medical device back into the patient's body. While the cover can be little longer than the working element of the medical device, it is anticipated that the cover may be significantly longer than that working element. This will permit an operator greater flexibility in using the device without adding unduly to the cost.

Figure 12 schematically illustrates the next stage of the method of removing the medical device from the patient's vascular system. In this view, the retrieval sheath has been moved distally with respect to the cover. As suggested above, this may be achieve either by moving the retrieval sheath distally along the cover or by withdrawing the cover (and, optimally, the medical device) proximally while holding the retrieval sheath 20 stationary. Urging the retrieval sheath distally with respect to the cover urges the cover to collapse about the medical device received therein. This causes the cover to tightly engage the surface of the medical device, helping better encase any particular matter received within the enclosure and limit the likelihood that it may spill back into the patient's vascular system. It also presents the device with a radially reduced profile, making it easier to withdraw the device from the patient's body without undue trauma.

Looking at the device in Figure 12, the system has a particular configuration which is unique to the present invention. In this configuration, the working element of the medical device is completely retained within the recess 38 of the body 31 of the cover such that the distal end 36 of the cover 30 is

positioned distally beyond the distal end of the working element 12. In Figure 12, at least a proximal length of the basket 12 and the body 31 of the cover are retained within the lumen of the retrieval sheath 20. This retrieval sheath radially compresses the proximal length of the cover such that an intermediate portion of the generally tubular wall 34 of the body 31 tightly engages a surface of the basket 12.

If so desired, the cover 30 and basket 12 may be further retracted so that they are both completely enclosed within the lumen of the retrieval sheath 20 prior to withdrawing the device from the patient's vessel. This is not necessary for effective operation of the current device, though, and may be left up to the physician's choice during the procedure. It should also be noted that the configuration shown in Figure 12 may be further collapsed by withdrawing the basket 12, cover 30 and retrieval sheath 20 proximally into the deployment catheter C, thereby further encasing the emboli and making it easier to withdraw the device from the vascular system.

Figure 7 illustrates one problem which could be encountered in deploying a medical device retrieval system 10 of the invention across a vascular obstruction. The vascular obstruction in Figure 7 is typified as a stent 4 having a stenotic lesion 6 partially occluding the lumen thereof, but this is selected merely for illustration. Much the same problem could also be encountered with a variety of other vascular obstructions.

The illustrated deployment sheath 20 has a blunt distal tip 22′. Due to the curvature of the vessel where the stent is located, the retrieval sheath tends to drift upwardly toward the outside of the curve rather than easily tracking the shaft 14 of the medical device through the center of the vessel. This problem becomes even more pronounced if the retrieval sheath is made stiffer, such as by incorporating metallic braid into the wall of the sheath, to improve pushability. In some instances, it can take undue time and effort to manipulate the distal tip of the retrieval sheath to clear the obstruction. In addition, use of excess force or movement of the sheath to clear the obstruction risks displacing the working

element (not shown) of the medical device from the treatment site where it has been deployed.

Figures 13 and 14 illustrate two proposed solutions to ameliorate these deployment difficulties. A first solution is illustrated in Figure 13 while Figure 14 illustrates another improvement which may be used alone or in conjunction with the device of Figure 13.

Turning first to Figure 13, the retrieval sheath 20 shown therein includes a deployment stylet 70 slidably received in the lumen 24 thereof. This stylet has a lumen 75 within which the shaft 14 of the medical device is received, permitting the stylet to slide along that shaft 15 with the retrieval sheath 20. The stylet 70 is provided with an elongate tubular body 72 and a tapering distal tip 74. In use, the body 72 of the stylet desirably extends along the entire length of the retrieval sheath so that the proximal end of the sheath (not shown) extends proximally beyond the proximal end of the retrieval sheath so an operator may selectively control the stylet independently of the guide wire and of the retrieval sheath.

The distal tip 74 of the stylet tapers from its proximal end 76 to its distal end 78. At its proximal end, the distal tip has an outer diameter which approximates the diameter of the lumen 24 of the retrieval sheath at the distal end 22 thereof. As illustrated, it is not intended that the stylet 70 completely fill the lumen 24 of the sheath as that would lead to undue friction in moving the stylet relative to the sheath. The outer diameter of the sheath at the proximal end 76 of the tip 74 need only be close enough to the diameter of the distal lumen of the sheath 20 to avoid a sharp, traumatic change in diameter which would be likely to catch on vascular obstructions and hinder deployment of the sheath 20 in the vessel. The transition from the distal tip 74 of the stylet to the outer diameter of the sheath 20 can be further eased by proving the distal tip 22 of the sheath 20 with a beveled distal end.

The distal end 78 of the stylet's distal tip 74 has an outer diameter which more closely approximates the outer diameter of the medical device shaft 14. It is not expected that this distal end 78 be infinitely thin and track directly against the surface of the shaft 14. Again, it is sufficient that the distal end 78 of the

stylet be close enough to the diameter of the shaft 14 of the medical device to avoid a sharp, traumatic change in diameter which would be likely to catch on vascular obstructions and hinder deployment of the sheath 20 in the vessel.

When the stylet is deployed such that its distal tip 74 extends distally beyond the distal tip 22 of the retrieval sheath, the stylet provides a transition between the shaft 14 of the medical device and the distal end of the retrieval sheath 20. This makes it easier to track the shaft 14 and guide the device into position across a vascular obstruction. Figure 13 illustrates the stylet positioned such that the proximal end 76 of the distal tip 74 is positioned immediately adjacent the distal tip 22 of the retrieval sheath, but this is not necessary. If the body 72 of the stylet has a substantially constant diameter over the relevant length, the stylet can be moved distally relative to the sheath 20 such that the body extends beyond the distal end of the sheath. This will not case any undue problem as the outer diameter of the body is desirably substantially the same as the outer diameter of the proximal end 76 of the distal tip.

Use of the retrieval sheath 20 with the stylet 70 can be varied. If so desired, one can use the stylet in each and every deployment of the retrieval system of the invention. However, as outlined below, use of the stylet adds an additional step to the retrieval process and its use may be reserved for those circumstances where the operator either expects to encounter a vascular obstruction or has already encountered such an obstruction.

In use, the stylet 70 and the cover 30 are exchangeable for one another, i.e., either the stylet or the cover may track along the shaft 14 within the lumen 24 of the retrieval sheath, but both cannot be used at the same time. Instead, one must be removed and replaced with the other. If the operator anticipates a vascular obstruction (or he or she wants to avoid exchanging devices twice if an obstruction is encountered), he or she can initially deploy the sheath 20 with the stylet. This may be accomplished by positioning the stylet 70 with respect to the sheath 20 such that the distal tip 74 of the stylet extends distally beyond the distal tip 22 of the sheath. Optimally, both the stylet and the sheath are advanced together along the shaft 14 until the distal tip 22 of the sheath is in a

desired position with respect to the working element of the medical device. (In most circumstances, this will be at a location wherein the distal tip of the sheath is near the working element, but spaced proximally therefrom, as discused above in connection with Figure 11.)

Once the sheath is in position, the stylet 70 may be exchanged for the cover 30. This may be done in much the same fashion that catheters are exchanged in a typical balloon angioplasty procedure or the like. In most circumstances, an exchange wire will be attached to the proximal end of the shaft 14 of the medical device and the stylet 70 can be retracted proximally onto the exchange wire. Thereafter, the exchange wire can be disconnected and the cover may be advanced along the shaft 14 through the lumen 24 of the retrieval sheath. Using the marker band 26 of the retrieval sheath and the marker band 13 of the basket 12 (for example), any final adjustments to the position of the sheath with respect to the working element of the medical device can be made prior to deployment of the cover.

The cover may then be moved distally with respect to the sheath 20, either by distally advancing the cover or proximally retracting the sheath. As noted above, this permits the body 31 of the cover to radially expand into a deployed configuration wherein the distal end remains distally open and the enclosure is radially expanded. The cover may then be moved distally with respect to the working element of the medical device and into engagement with a surface of the medical device to form therebetween an enclosure. Optimally (but not necessarily, depending on the configuration of the medical device and the shape of the cover), the cover is advanced further with respect to the working element until the entire working element is effectively received in the recess 38 of the cover. Thereafter, the retrieval sheath is moved distally with respect to the cover to urge the cover to collapse about the working element and tightly engage the surface of the working element to retain any debris in the enclosure.

Figure 14 illustrates another improvement of the sheath 20 of the invention. In this embodiment, a distal length 21 of the sheath 20 is bent at an

angle with respect to the body of the sheath. If a vascular obstruction is encountered, this distal bend will permit the operator to clear the obstruction by reorienting the sheath so that the distal tip 22 thereof is spaced toward the center of the vessel and away from the obstruction, whereupon the sheath can be further advanced. An angle of between about 5 and about 30° is believed to be sufficient for most purposes without unduly interfering with the proper deployment and retrieval of the cover 30. The length of the distal length 21 can be varied as needed. In most circumstances, it is envisioned that the distal length 21 will be 5 cm or less, with a length of 1 cm to 3 cm being most likely. As noted previously, the sheath 20 of Figure 14 with its bent distal length 21 may be used instead of or in conjunction with the stylet 70 shown in Figure 13.

While a preferred embodiment of the present invention has been described, it should be understood that various changes, adaptations and modifications may be made therein without departing from the spirit of the invention and the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A medical device retrieval system, comprising:

a) a medical device comprising a working element carried by a flexible, elongate shaft, the working element having a proximal profile and the shaft extending proximally from the working element; and

b) a retrieval cover slidably carried along the shaft of the medical device, the cover having a deployed configuration and being capable of being compressed into a compressed configuration for deployment, yet resiliently substantially return to the deployed configuration; the cover in its deployed configuration having a radially reduced proximal portion, a distally open distal end defining a distal opening having a maximum dimension at least as great as the maximum dimension of the proximal profile of the working element of the medical device, and an elongate internal recess defined between the proximal portion and the distal end; the cover in its compressed configuration being radially compressed inwardly toward the shaft and being distally open with the distal end defining the distal-most portion of the cover.

2. The system of claim 1 further comprising a retrieval sheath, the retrieval sheath being slidable along the shaft of the medical device and being positioned distally of the cover when the cover is in its deployed configuration.

3. The system of claim 2 where in the retrieval sheath has an inner diameter smaller than an outer diameter of the cover in its deployed configuration, the sheath being adapted to slide distally along the cover to compress the cover about the medical device.

4. The system of claim 2 wherein the retrieval sheath has a body and a distal tip comprising a distal length of the retrieval sheath, the distal tip being bent at an angle of between about 5 and about 30° with respect to the body.

5. The system of claim 4 wherein the distal tip is between about 1 cm and about 5 cm in length.

6. The system of claim 4 wherein the distal tip further comprises a radiopaque marker band.

7. A medical device retrieval system, comprising:

a) a medical device comprising a working element carried by a flexible, elongate shaft having an outer diameter, the working element having a proximal profile and the shaft extending proximally from the working element;

b) a retrieval sheath being slidable along the shaft of the medical device, the retrieval sheath having a beveled distal end with a distal lumen;

c) a deployment stylet slidable along the shaft of the medical device, the deployment stylet having a distal tip tapering distally from a first diameter approximating a diameter of the distal lumen of the sheath to a second diameter more closely approximating the outer diameter of the medical device shaft, providing a transition between the shaft of the medical device and the distal end of the retrieval sheath when the deployment stylet is positioned such that the distal tip extends distally beyond the distal end of the retrieval sheath; and

d) a retrieval cover slidable along the shaft of the medical device and being exchangeable for the stylet therealong, the cover having a deployed configuration and being capable of being compressed into a compressed configuration for siding within the lumen of the retrieval sheath yet resiliently substantially return to the deployed configuration; the cover in its deployed configuration having a radially reduced proximal portion, a distally open distal end defining a distal opening having a maximum dimension at least as great as the maximum dimension of the proximal profile of the working element of the medical device, and an elongate internal

recess defined between the proximal portion and the distal end; the cover in its compressed configuration being radially compressed inwardly toward the shaft and being distally open with the distal end defining the distal-most portion of the cover.

8. A retractable medical device system, comprising:

a) a medical device comprising a working element carried by a flexible, elongate shaft;

b) a retrieval cover slidable along the shaft of the medical device, the cover having a radially reduced proximal portion, a distally open distal end and an elongate tubular wall extending therebetween and defining a recess; the working element of the medical device being completely retained within the recess of the cover such that the tubular wall extends distally beyond the medical device; and

c) a retrieval sheath, the retrieval sheath having a lumen and being slidable with respect to both the medical device and the cover, at least a proximal length of the working element of the medical device and the cover being retained within the lumen of the retrieval sheath, the retrieval sheath radially compressing the proximal length of the cover such that an intermediate portion of the wall tightly engages a surface of the medical device.

9. A method of retrieving particulate or other foreign material within a channel of a patient's body, comprising:

a) providing a medical device having a working element and a flexible, elongate shaft adapted to follow a path within the channel; a distally open cover slidable with respect to the shaft; and a retrieval sheath moveable with respect to the cover and the shaft;

b) positioning the medical device within the vessel to engage a wall of the channel and trap the material within the channel, the cover and the retrieval sheath being spaced proximally of the working element along the shaft of the medical device, the cover being radially compressed within the lumen of the retrieval sheath such

that it has a distally open distal end and a wall defining a recess, the wall engaging an inner surface of the retrieval sheath;

c) moving the cover distally with respect to the retrieval sheath, thereby permitting the cover to radially expand into a deployed configuration wherein the distal end remains distally open and the enclosure is radially expanded, the cover expanding radially outwardly into the deployed configuration without having to invert on itself;

d) moving the cover distally with respect to the medical device and into engagement with a surface of the medical device to form therebetween an enclosure;

e) moving the retrieval sheath distally with respect to the cover to urge the cover to collapse about the medical device and tightly engage the surface of the medical device.

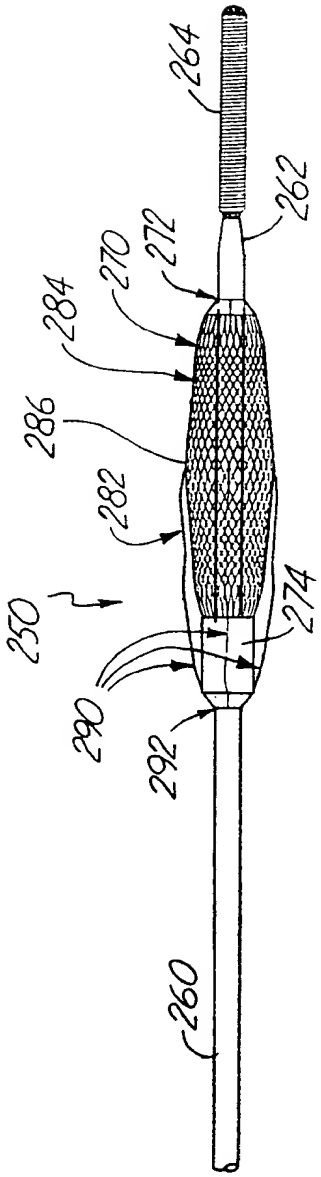
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Fig. 1A

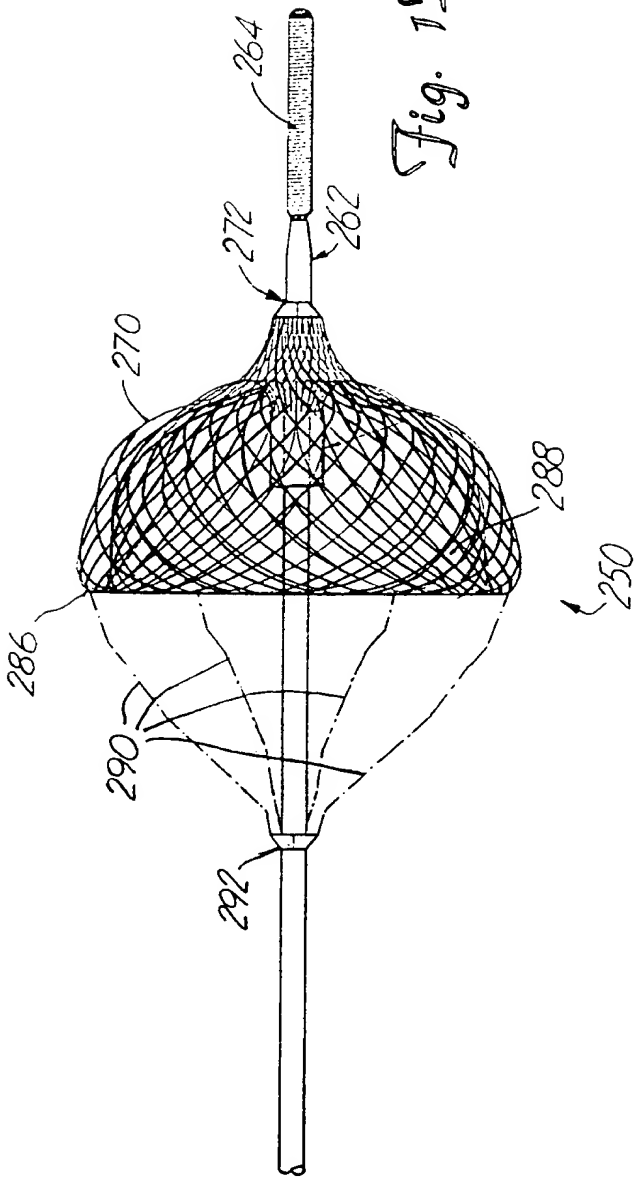
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Fig. 1B

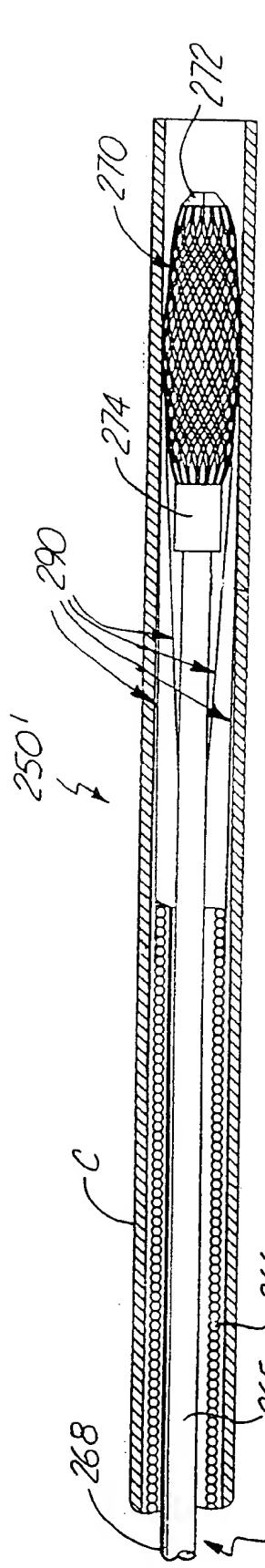
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Fig. 2A

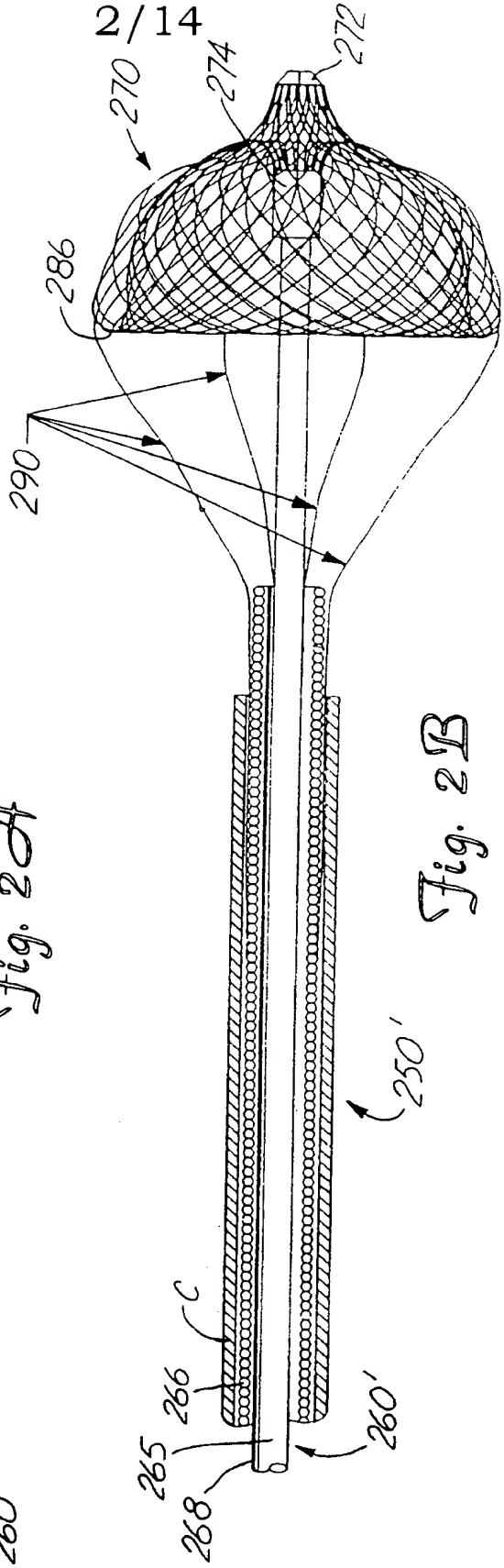
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Fig. 2B

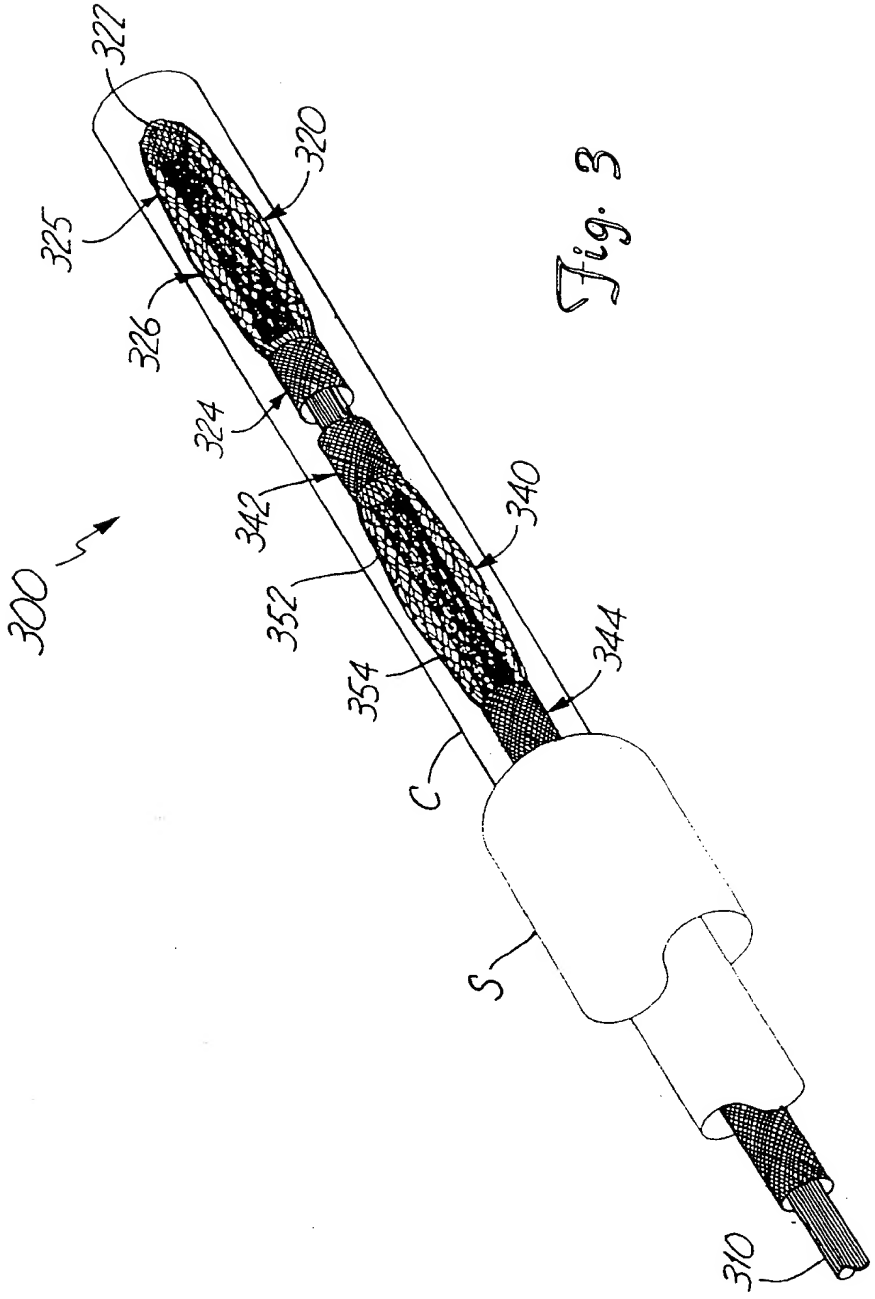

Fig. 3

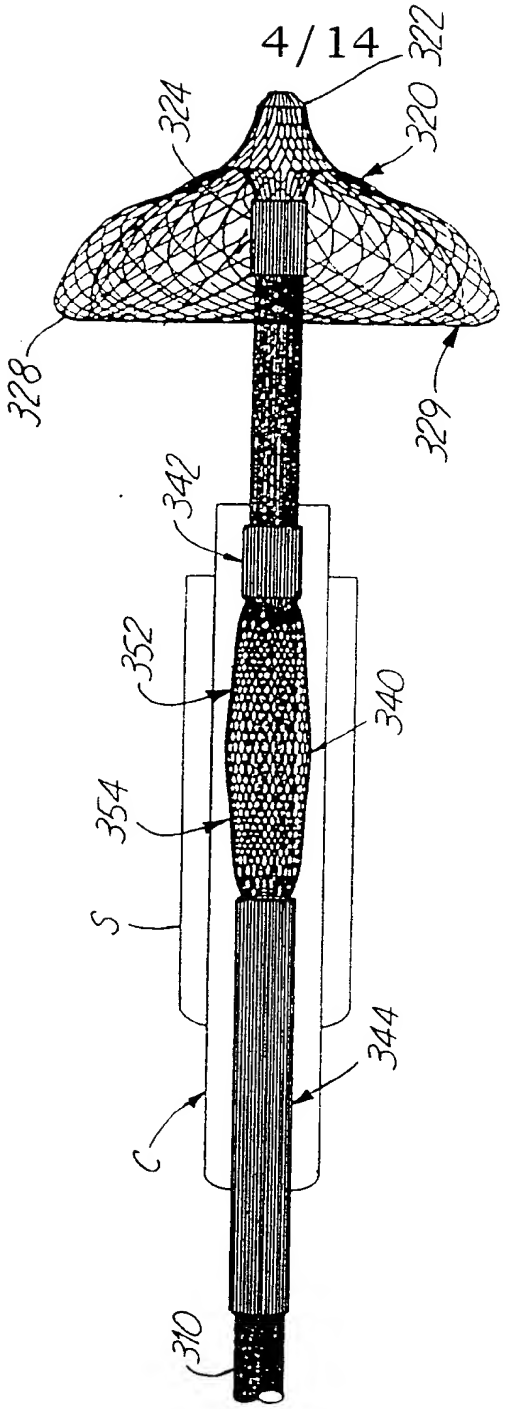

Fig. 4

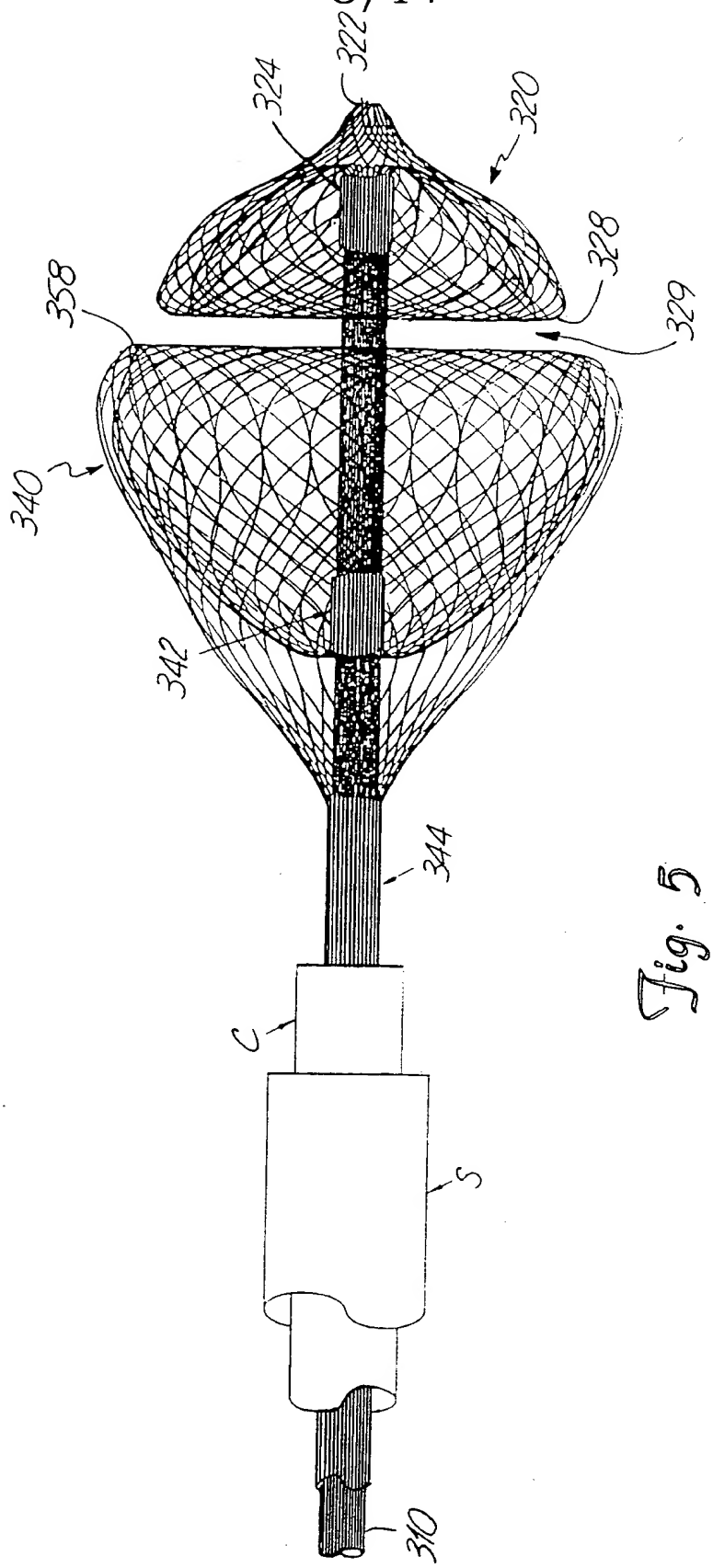

Fig. 5

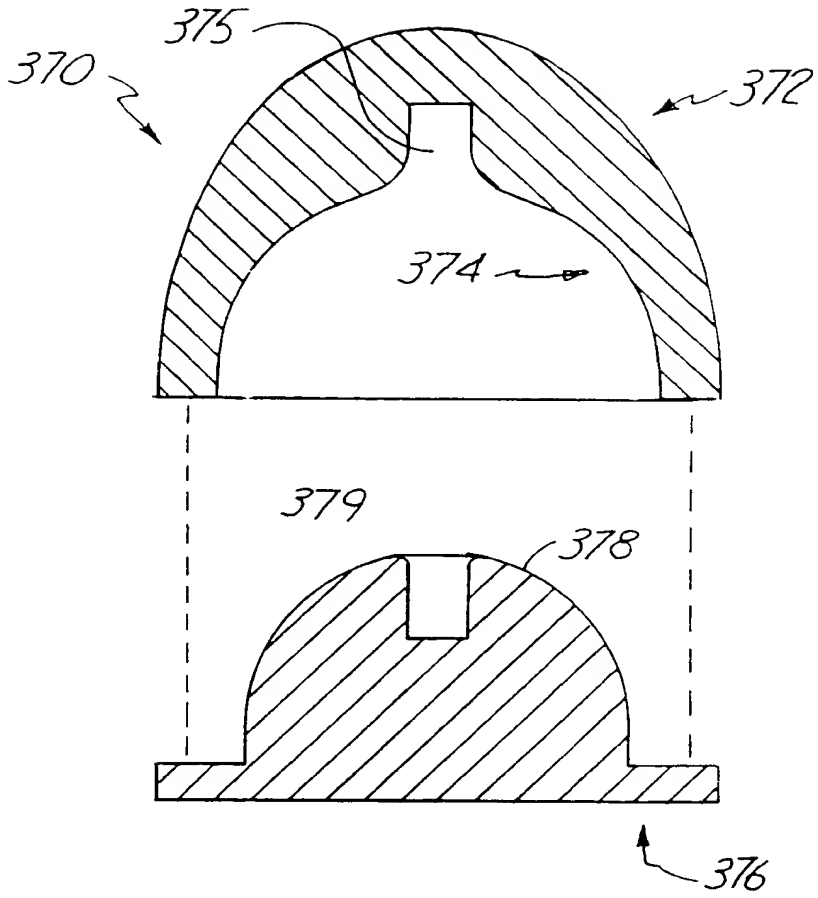

Fig. 6

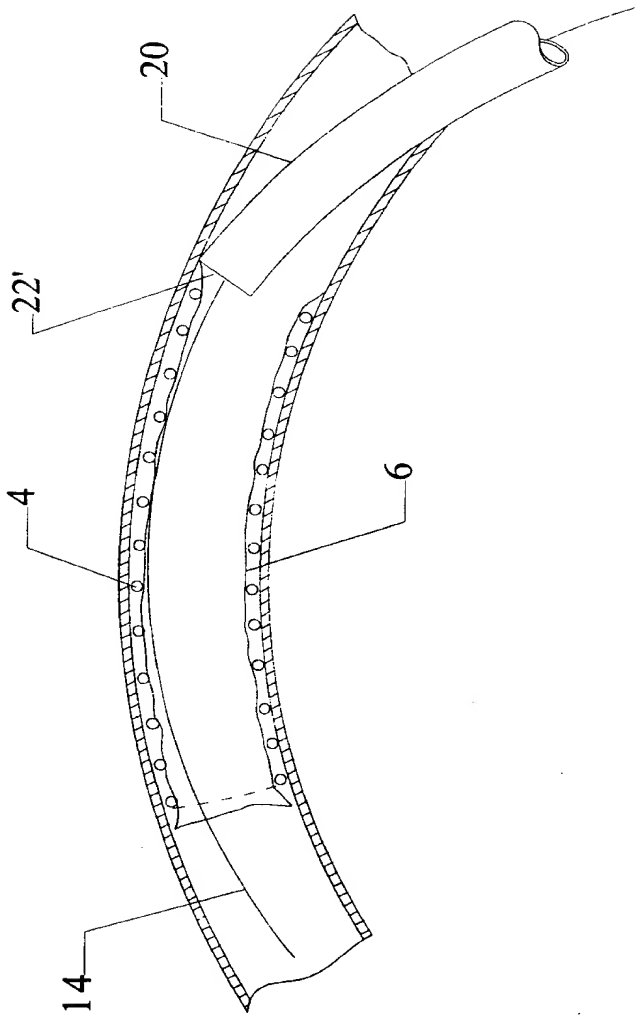

FIG. 7

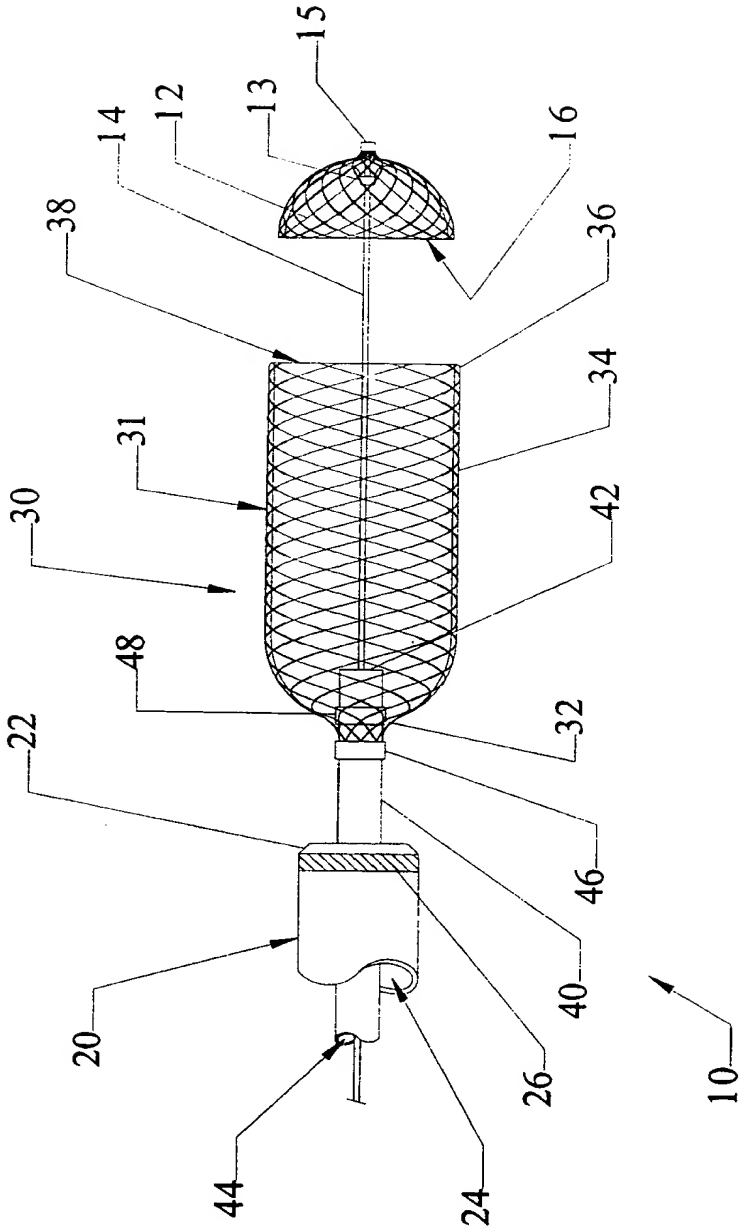

FIG. 8

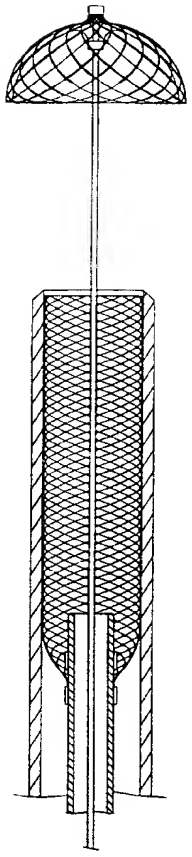

FIG. 9

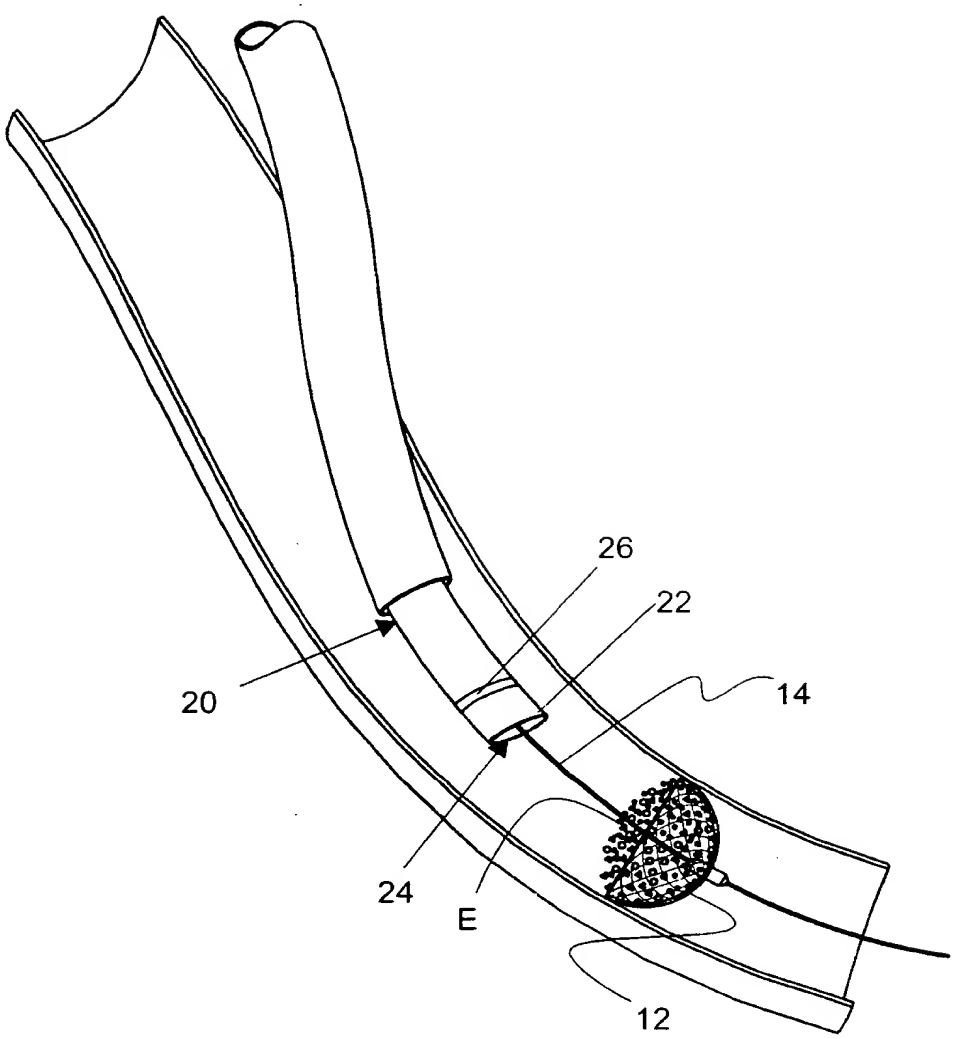

FIG. 10

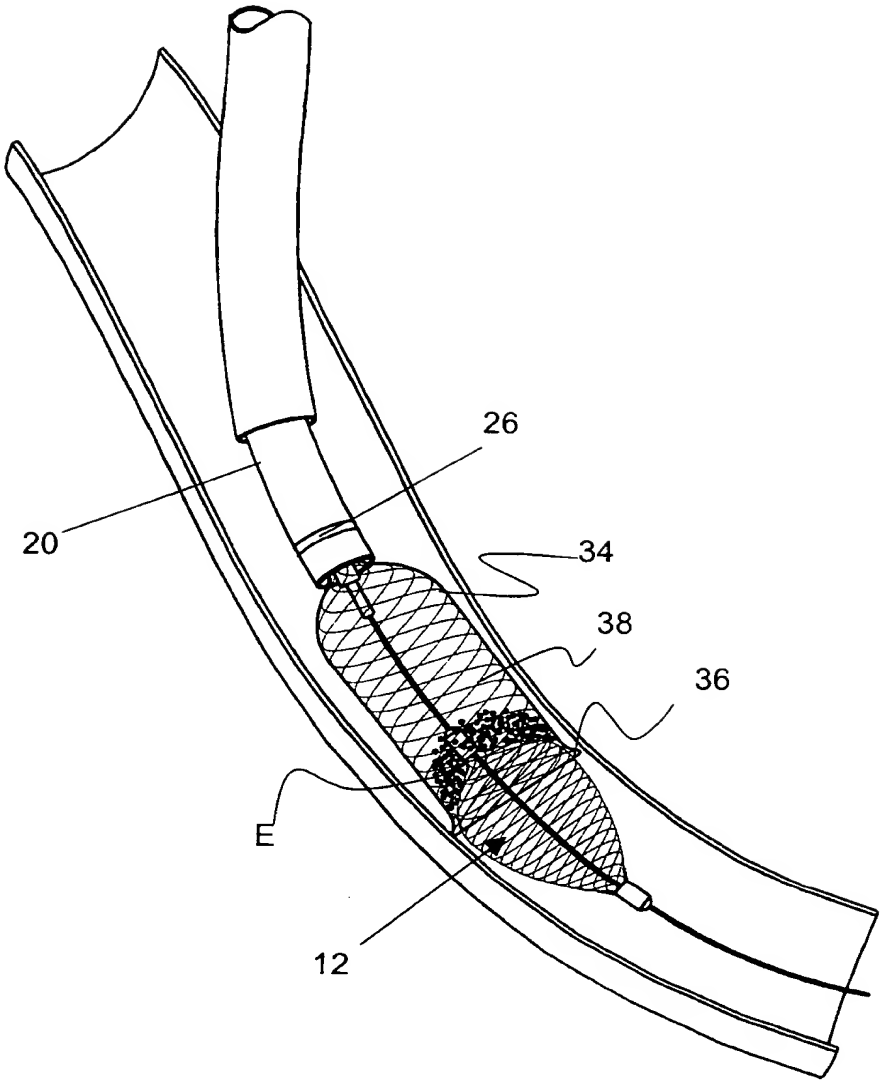

FIG. 11

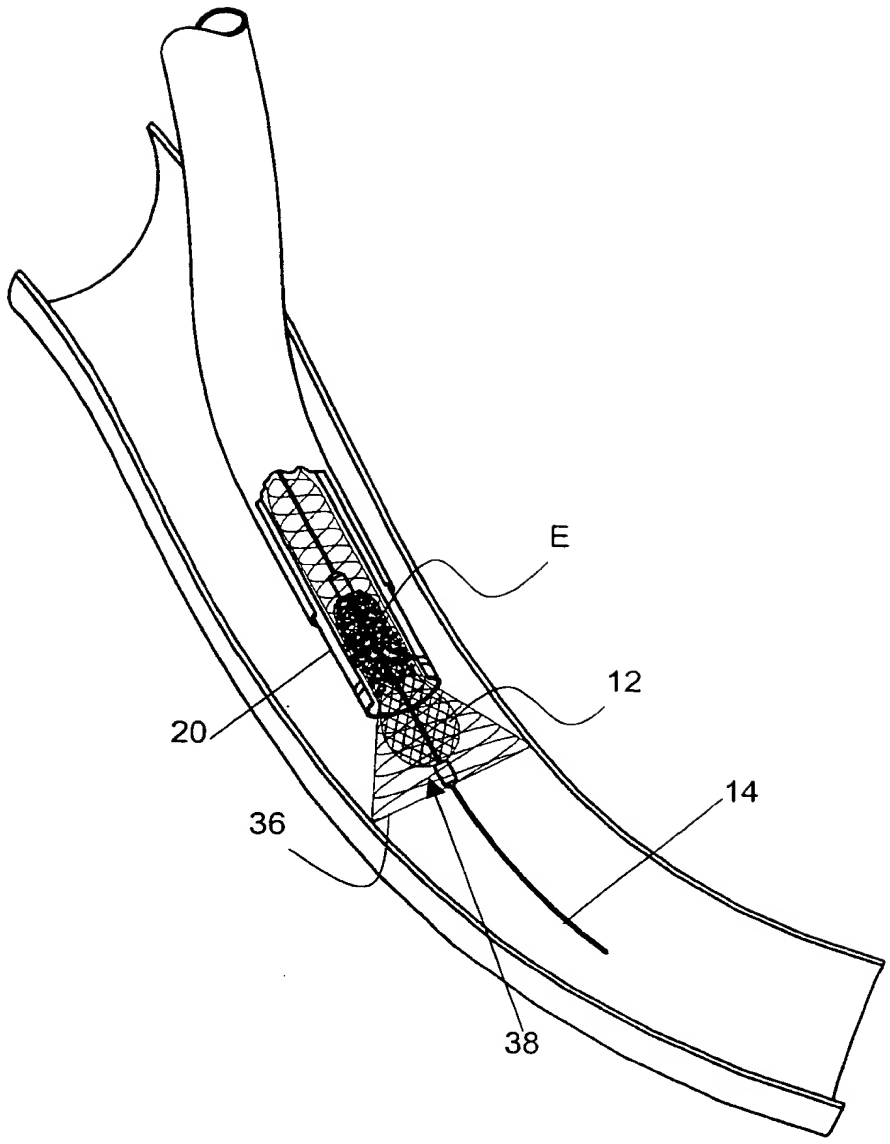

FIG. 12

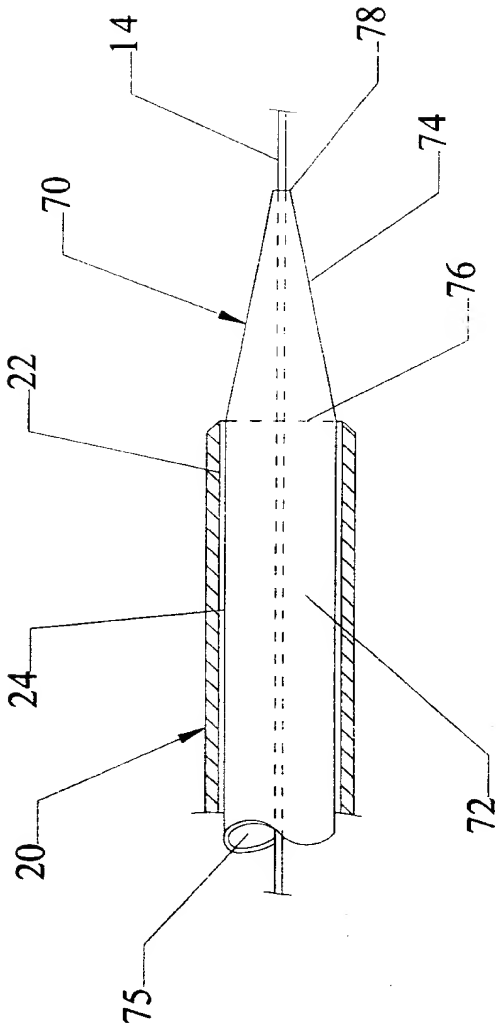

FIG. 13

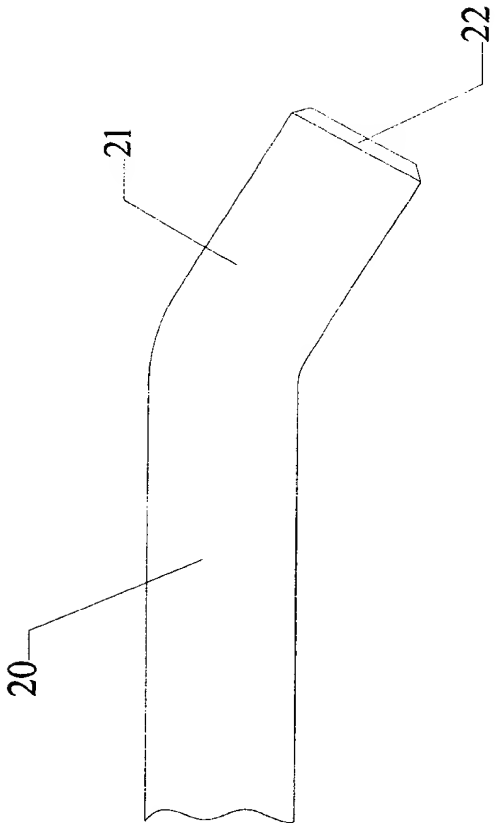

FIG. 14

INTERNATIONAL SEARCH REPORT

Inte ional Application No
PCT/US 00/06212

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/01 A61B17/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 102 415 A (VORWERK DIERK ET AL) 7 April 1992 (1992-04-07)	1-3
Y	the whole document	7,8
Y	WO 91 11209 A (BOSTON SCIENT CORP) 8 August 1991 (1991-08-08)	7,8
A	page 8, line 32 -page 9, line 15; figure 1	1
X	US 5 662 671 A (PASTRONE GIOVANNI ET AL) 2 September 1997 (1997-09-02)	1-4
A	abstract; figure 1	7,8
A	WO 96 01591 A (MICROVENA CORP) 25 January 1996 (1996-01-25) cited in the application abstract; figure 15	1-8

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 July 2000	12/07/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Hansen, S

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

information on patent family members

Inter ɔnal Application No
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